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Presidential Documents

Title 3—

The President

Proclamation 9442 of May 5, 2016

Military Spouse Appreciation Day, 2016

By the President of the United States of America

A Proclamation

Serving alongside our Soldiers, Sailors, Airmen, Marines, and Coast Guardsmen, our Nation's military families give of themselves and give up their time with their loved ones so we may live safely and freely. Few Americans fully understand the sacrifices made by those who serve in uniform, but for spouses of service members across our country, the costs of the freedom we too often take for granted are known intimately. On Military Spouse Appreciation Day, we honor the spouses of those who have left behind everything they know and love to join our Nation's unbroken chain of patriots, and we recommit to giving military spouses the respect, dignity, and support they deserve.

Enduring separation and relocation, heartache and anticipation, military spouses demonstrate a strength reflective of the spirit of our Nation. The spouses of our men and women in uniform bear the burden of sustaining their families, caring for children and offering comfort and support while their loved ones are away. As a country, we must keep faith with military spouses and uphold our commitment to the members of our Armed Forces to look after their families.

Five years ago, First Lady Michelle Obama and Dr. Jill Biden launched the Joining Forces initiative. Through Joining Forces, my Administration is working to ensure the spouses of our men and women in uniform have good, secure jobs so they can better provide for their families. We launched the Military Spouse Employment Partnership—uniting hundreds of businesses across America in a collaborative effort to employ more military spouses. Additionally, I proposed an increase in funding to help address the barriers that too often hold back transitioning service members and their spouses from greater economic possibility. And I have taken action to improve access to mental health care for our veterans and their families, and to ensure they are able to find adequate housing—because anyone who defended America should have a home in America. I encourage all people to visit www.JoiningForces.gov to learn how to get involved or for more information.

Military spouses exhibit tremendous courage and unyielding faith, and in their spirit of resolve, we see the best of America. Let us celebrate these selfless individuals by supporting them and upholding our everlasting commitment to stand beside them and their families.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim May 6, 2016, as Military Spouse Appreciation Day. I call upon the people of the United States to honor military spouses with appropriate ceremonies and activities.

IN WITNESS WHEREOF, I have hereunto set my hand this fifth day of May, in the year of our Lord two thousand sixteen, and of the Independence of the United States of America the two hundred and fortieth.

Rules and Regulations

Federal Register
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SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 230 and 240

[Release No. 33–10075; 34–77757; File No. S7–12–14]

RIN 3235–AL40

Changes to Exchange Act Registration Requirements To Implement Title V and Title VI of the JOBS Act

AGENCY: Securities and Exchange Commission.

ACTION: Final rule.

SUMMARY: We are amending our rules in light of the statutory changes made by Title V and Title VI of the Jumpstart Our Business Startups Act (the "JOBS Act") and Title LXXXV of the Fixing America's Surface Transportation Act (the "FAST Act"). The amendments revise our rules to reflect the new, higher thresholds for registration, termination of registration and suspension of reporting that were set forth in the JOBS Act and the FAST Act. In addition, the amendments revise the definition of "held of record" in Rule 12g5–1 under the Securities Exchange Act of 1934 (the "Exchange Act"), in accordance with the JOBS Act, to exclude certain securities held by persons who received them pursuant to employee compensation plans and establish a non-exclusive safe harbor for determining whether securities are "held of record" for purposes of registration under Exchange Act Section 12(g).

DATES: Effective June 9, 2016.

FOR FURTHER INFORMATION CONTACT: Steven G. Hearne, Senior Special Counsel, at (202) 551–3430, or Anne Krauskopf, Senior Special Counsel, at (202) 551–3500, Division of Corporation Finance, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549.

SUPPLEMENTARY INFORMATION: We are adopting amendments to Rules 3b–4,[1] 12g–1,[2] 12g–2,[3] 12g–3,[4] 12g–4,[5] 12g5–1,[6] and 12h–3[7] under the Exchange Act[8] and amendments to Rule 405[9] under the Securities Act of 1933 (the "Securities Act").[10]

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On December 17, 2014, we proposed amendments[11] to implement Title V and Title VI of the JOBS Act.[12] The JOBS Act amended Sections 12(g)[13] and 15(d)[14] of the Exchange Act to adjust the thresholds for registration, termination of registration and suspension of reporting.[15] Specifically, Section 501 of the JOBS Act[16] amended Section 12(g)(1) of the Exchange Act[17] to require an issuer to register a class of equity securities (other than exempted securities) within 120 days after its fiscal year-end if, on the last day of its fiscal year, the issuer has total assets of more than $10 million and the class of equity securities is "held of record" by either (i) 2,000 persons, or (ii) 500 persons who are not accredited investors. Section 601 of the JOBS Act[18] further amended Exchange Act Section 12(g)(1) to require an issuer that is a bank or a bank holding company, as defined in Section 2 of the Bank Holding Company Act of 1956,[19] to register a class of equity securities (other than exempted securities) within 120 days after the last day of its first fiscal year ended after the effective date of the JOBS Act, on which the issuer has total assets of more than $10 million and the class of equity securities is "held of record" by 2,000 or more persons. Section 601 of the JOBS Act also amended Exchange Act Section 12(g)(4)[20] and Exchange Act Section 15(d)(1)[21] to enable an issuer that is a bank or a bank holding company to terminate the registration of a class of securities under Section 12(g) or suspend reporting under Section 15(d)(1) if that class is held of record by less than 1,200 persons.[22] For other issuers, the threshold in Section 12(g)(4) for termination of registration and in Section 15(d)(1) for suspension of reporting remained at 300.[23] In addition, Section 502 of the JOBS Act[24] amended Exchange Act Section 12(g)(5)[25] to exclude from the definition of "held of record," for the purposes of determining whether an issuer is required to register a class of equity securities, securities that are held by persons who received them pursuant to an "employee compensation plan" in transactions exempted from the registration requirements of Section 5 of the Securities Act.[26] Section 503 of the JOBS Act [27] directed the Commission to revise the definition of "held of record" pursuant to Exchange Act Section 12(g)(5) to implement the amendment made by Section 502 of the JOBS Act, and to create a safe harbor for issuers when determining whether holders received their securities pursuant to an "employee compensation plan" in a transaction exempted from the registration requirements of Section 5 of the Securities Act.

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[1] 17 CFR 240.3b–4.

[2] 17 CFR 240.12g–1.

[3] 17 CFR 240.12g–2.

[4] 17 CFR 240.12g–3.

[5] 17 CFR 240.12g–4.

[6] 17 CFR 240.12g5–1.

[7] 17 CFR 240.12h–3.

[8] 15 U.S.C. 78a *et seq.*

[9] 17 CFR 230.405.

[10] 15 U.S.C. 77a *et seq.*

[11] *Changes to Exchange Act Registration Requirements to Implement Title V and Title VI of the JOBS Act,* Release No. 33–9693 (Dec. 17, 2014) [79 FR 78343 (Dec. 30, 2014)] (the "Proposing Release").

[12] Public Law 112–106, 126 Stat. 306 (Apr. 5, 2012).

[13] 15 U.S.C. 78*l*(g).

[14] 15 U.S.C. 78*o*(d).

[15] The changes to Exchange Act Sections 12(g)(1), 12(g)(4) and 15(d)(1) were effective upon enactment of the JOBS Act and do not require any Commission action.

[16] Sec. 501, 126 Stat. at 325.

[17] 15 U.S.C. 78*l*(g)(1).

[18] Sec. 601, 126 Stat. at 326.

[19] 12 U.S.C. 1841.

[20] 15 U.S.C. 78*l*(g)(4).

[21] 15 U.S.C. 78*o*(d)(1).

[22] *See supra* note 18.

[23] *See* 15 U.S.C. 78*l*(g)(4) and 15 U.S.C. 78*o*(d)(1).

[24] Sec. 502, 126 Stat. at 326.

[25] 15 U.S.C. 78*l*(g)(5).

Subsequent to our proposal, Section 85001 of the FAST Act [28] adjusted the Exchange Act thresholds for registration, termination of registration and suspension of reporting for savings and loan holding companies, as defined in Section 10 of the Home Owners' Loan Act,[29] so that they would be the same as the thresholds for banks and bank holding companies. This change also was effective upon enactment.

In connection with the amendments made by Title V and Title VI of the JOBS Act and Title LXXXV of the FAST Act, we are amending our rules to reflect the new, higher registration, termination of registration and suspension of reporting thresholds under amended Exchange Act Sections 12(g)(1), 12(g)(4) and 15(d)(1). We are also amending Exchange Act Rule 12g5–1 to reflect the amendment to Exchange Act Section 12(g)(5) and to establish a non-exclusive safe harbor that issuers may follow when determining if securities held by persons who received them pursuant to an employee compensation plan in transactions exempted from the registration requirements of Section 5 of the Securities Act may be excluded when determining whether they are required to register under Exchange Act Section 12(g)(1).

The comment period for the proposed amendments closed on March 2, 2015. We received 11 comment letters on the Proposing Release, which generally supported the proposals.[30] We have reviewed and considered all of these comments. We are adopting the amendments substantially as proposed, and discuss these amendments and any modifications or clarifications in detail below.

II. Amendments Relating to Exchange Act Reporting Thresholds

A. Application of the Increased Thresholds for Registration and Reporting Obligations

Sections 501 and 601 of the JOBS Act amended the Exchange Act to raise the total assets and held of record thresholds under which issuers are required to register or permitted to terminate registration or suspend reporting pursuant to Section 12(g) and 15(d) of the Exchange Act. Section 85001 of the FAST Act further amended these provisions to apply the new statutory thresholds for banks and bank holding companies to savings and loan holding companies.

1. Proposed Rule Amendments

To harmonize our rules with the statutory changes made to Exchange Act Sections 12(g)(1), 12(g)(4) and 15(d), we proposed amendments to Exchange Act Rules 12g–1, 12g–2, 12g–3, 12g–4 and 12h–3, the rules that govern the mechanics relating to registration, termination of registration under Section 12(g) and suspension of reporting obligations under Section 15(d). These rules generally reflected the holder of record statutory thresholds in Sections 12(g) and 15(d) prior to the enactment of the JOBS Act.[31]

We proposed to revise Rule 12g–1 to reflect the asset and holder of record thresholds established by Titles V and VI of the JOBS Act relating to the requirement to register a class of equity securities under the Exchange Act.[32] Similarly, we proposed to revise Exchange Act Rules 12g–2 [33] and 12g–3 [34] to reflect the holders of record thresholds in the Exchange Act, as amended by the JOBS Act, for terminating registration and suspending reporting for banks and bank holding companies. In addition, we proposed to amend Exchange Act Rules 12g–4 and 12h–3, the rules which permit issuers to immediately suspend their duty to file periodic and current reports, to reflect the new thresholds in Sections 12(g) and 15(d) enacted by the JOBS Act for banks and bank holding companies.

In light of the fact that savings and loan holding companies provide similar services to banks and bank holding companies and are generally subject to similar bank regulatory and supervision requirements, we also proposed to use our general exemptive authority to apply the same registration thresholds applicable to banks and bank holding companies to savings and loan holding companies and to revise our rules accordingly. As noted above, subsequent to this proposal, the FAST Act amended the Exchange Act to apply the new statutory thresholds for banks and bank holding companies to savings and loan holding companies.[35]

Because the new statutory threshold for banks, savings and loan holding companies and bank holding companies is not reflected in our existing rules, such institutions seeking to rely on the new 1,200 holder of record threshold to terminate registration and suspend reporting are not able to rely on the existing procedural accommodations in our rules to do so immediately. Without the proposed amendments, a bank, savings and loan holding company or bank holding company is required to wait 90 days after filing a certification with the Commission that the number of its holders of record is less than 1,200 persons to terminate its Section 12(g) registration and cease filing reports required by Exchange Act Section 13(a),[36] rather than being able to suspend its Section 13(a) reporting obligations immediately upon the filing of a Form 15 [37] in reliance on the rule. Similarly, without the proposed amendments, banks, savings and loan holding companies or bank holding companies may not rely on Rule 12h–3 to immediately suspend their Section 15(d) reporting obligations using the new higher statutory threshold during a fiscal year. Rather, Section 15(d)(1) provides for suspending a Section 15(d) obligation only at the beginning of a fiscal year.

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[26] 15 U.S.C. 77e.

[27] Sec. 503, 126 Stat. at 326.

[28] Public Law 114–94 (Dec. 4, 2015).

[29] 12 U.S.C. 1461.

[30] We also considered pre-proposal comment letters when formulating the proposed amendments. Pre-proposal comment letters received on Title V of the JOBS Act are available at *http://www.sec.gov/comments/jobs-title-v/jobs-title-v.shtml* and on Title VI of the JOBS Act at *http://www.sec.gov/comments/jobs-title-vi/jobs-title-vi.shtml.*

[31] Prior to adoption of the JOBS Act, the Commission used its general exemptive authority to provide for a $10 million asset threshold by rule. JOBS Act Section 501 amended Exchange Act Section 12(g)(1) to raise the statutory threshold from $1 million to $10 million to match the threshold previously provided in Exchange Act Rule 12g–1.

[32] We also proposed to remove the reference to an automated inter-dealer quotation system since the NASDAQ Stock Market is now registered as a securities exchange with the Commission. *See In the Matter of the Application of the Nasdaq Stock Market LLC for Registration as a National Securities Exchange; Findings, Opinion and Order of the Commission,* Release No. 34–53128 (Jan. 13, 2006) [71 FR 3550 (Jan. 23, 2006)].

[33] Rule 12g–2 addresses securities deemed to be registered pursuant to Section 12(g)(1) upon termination of certain exemptions.

[34] Rule 12g–3 addresses the threshold for the registration of securities of successor issuers under Section 12(b) or Section 12(g).

[35] Because of the FAST Act amendment to the Exchange Act, the Commission no longer needs to adopt changes relating to those thresholds using its general exemptive authority.

[36] 15 U.S.C. 78m(a).

[37] 17 CFR 249.323.

2. Comments on Proposed Rule Amendments

We received comments on the proposed amendments from two commenters.[38] These commenters supported the amendments as proposed. One commenter further agreed with our determination not to propose amendments to our rules relating to Exchange Act registration that extend substantially beyond the changes contemplated by the JOBS Act.[39] Several commenters also expressed support for our proposal to treat savings and loan holding companies similar to banks and bank holding companies for purposes of Exchange Act registration.[40]

3. Final Rule Amendments

After considering the comments, we are adopting the proposed amendments to Exchange Act Rules 12g–1, 12g–2, 12g–3, 12g–4 and 12h–3 to reflect the statutory changes made by the JOBS Act and the FAST Act. As amended, Rule 12g–1 provides that an issuer is not required to register a class of equity securities pursuant to Section 12(g)(1) if on the last day of its most recent fiscal year:

- The issuer had total assets not exceeding $10 million; or
- The class of equity securities was held of record by fewer than 2,000 persons or 500 persons who are not accredited investors (as such term is defined in Securities Act Rule 501(a)),[41] determined as of such day rather than at the time of the sale of the securities; or
- in the case of a bank; a savings and loan holding company, as such term is defined in section 10 of the Home Owners' Loan Act; or a bank holding company, as such term is defined in Section 2 of the Bank Holding Company Act of 1956, the class of equity securities was held of record by fewer than 2,000 persons.[42]

As revised, Rule 12g–2, which addresses securities deemed to be registered pursuant to Section 12(g)(1) upon termination of the exemption pursuant to Section 12(g)(2)(A) or (B)[43] and establishes a 300-person threshold for such a class of securities to be registered under Section 12(g), provides a 1,200-person registration threshold for a bank, a savings and loan holding company, as such term is defined in section 10 of the Home Owners' Loan Act, or bank holding company, as defined in Section 2 of the Bank Holding Company Act of 1956.

Revised Rule 12g–3, which addresses the 300-person threshold for the registration of securities of successor issuers under Section 12(b) or Section 12(g), similarly provides a 1,200-person registration threshold for a bank, a savings and loan holding company, as such term is defined in Section 10 of the Home Owners' Loan Act, or bank holding company, as defined in Section 2 of the Bank Holding Company Act of 1956.

Revised Rule 12g–4(a) provides that termination of registration under Section 12(g) shall take effect in 90 days, or such shorter period as the Commission determines, after the issuer certifies on Form 15 that the class of securities is held of record by fewer than 300 persons, 1,200 persons in the case of a bank, a savings and loan holding company, as such term is defined in section 10 of the Home Owners' Loan Act, or a bank holding company, as defined in Section 2 of the Bank Holding Company Act of 1956, or 500 persons where the total assets of the issuer have not exceeded $10 million on the last day of each of the preceding three years. As a result of the changes to Rule 12g–4(a), banks, savings and loan holding companies and bank holding companies will be able to terminate registration of a class of securities and suspend immediately their duty to file current and periodic reports upon filing a certification on Form 15 at the 1,200 person threshold.

Finally, revised Rule 12h–3 provides that the duty to file current and periodic reports under Section 13(a) pursuant to Section 15(d) for that class of securities is suspended immediately upon the filing of a certification on Form 15, provided that the issuer has fewer than 300 holders of record, 500 holders of record where the issuer's total assets have not exceeded $10 million on the last day of each of the preceding three years, or in the case of a bank, a savings and loan holding company, as such term is defined in Section 10 of the Home Owners' Loan Act, or bank holding company, as defined in Section 2 of the Bank Holding Company Act of 1956, 1,200 holders of record; the issuer has filed its Section 13(a) reports for the most recent three completed fiscal years, and for the portion of the year immediately preceding the date of filing the Form 15 or the period since the issuer became subject to the reporting obligation; and a registration statement has not become effective or was required to be updated pursuant to Exchange Act Section 10(a)(3)[44] during the fiscal year.[45]

B. Application of the Increased Threshold for Accredited Investors

Section 501 of the JOBS Act amended Exchange Act Section 12(g)(1) to increase the threshold that triggers registration by an issuer other than a bank or bank holding company to total assets exceeding $10 million and a class of equity securities (other than an exempted security) held of record by either 2,000 persons or 500 persons who are not accredited investors (as such term is defined by the Commission).[46] To rely on the new, higher threshold established by the JOBS Act, an issuer will need to be able to determine which of its record holders are accredited investors. A number of pre-proposal commenters pointed to potential compliance concerns with respect to identifying accredited investors and recommended ways to facilitate issuers' use of the increased threshold for holders of record that are accredited investors.[47]

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[38] *See* letters from American Bankers Association (Feb. 27, 2015) ("American Bankers") and American Bar Association (Apr. 10, 2015) ("ABA").

[39] *See* letter from ABA.

[40] *See* letters from American Bankers, ABA and Independent Community Bankers Association (Feb. 27, 2015) ("ICBA").

[41] 17 CFR 230.501(a).

[42] As observed by one commenter, Section 501 of the JOBS Act amended Section 12(g)(1) of the Exchange Act to require an issuer to register a class of equity securities (other than exempted securities) if, on the last day of its fiscal year, the issuer has total assets of more than $10 million and the class of equity securities is "held of record by either 2,000 persons, or 500 persons who are not accredited investors." *See* letter from Keith P. Bishop (Mar. 1, 2016). We read this language to provide that an issuer is not required to register under Section 12(g) if the issuer has fewer than 2,000 persons, or 500 persons who are not accredited investors that hold of record. An issuer with more than 2,000 persons, or 500 persons who are not accredited investors, that hold of record has necessarily met the threshold and would be required to register pursuant to Section 12(g)(1)(A).

[43] Section 12(g)(2)(A) [15 U.S.C. 78*l*(g)(2)(A)] provides an exemption from Section 12(g) registration while the class of securities is listed and registered on a national securities exchange under Exchange Act Section 12(b) [15 U.S.C. 78*l*(b)]. Section 12(g)(2)(B) [15 U.S.C. 78*l*(g)(2)(B)] provides an exemption for securities issued by registered investment companies.

[44] 15 U.S.C. 78j(a)(3).

[45] The automatic statutory suspension of an issuer's Section 15(d) reporting obligation also is not available as to any fiscal year in which the issuer's Securities Act registration statement becomes effective or is required to be updated pursuant to Section 10(a)(3) of the Securities Act.

[46] The statutory amendment was effective upon enactment of the JOBS Act and does not require any Commission action. While this change primarily affects issuers that have never had a reporting obligation under the Exchange Act, issuers that have terminated registration will need to monitor the accredited investor status of their holders of record as of the last day of each fiscal year.

[47] *See, e.g.*, letters from New York City Bar Association (June 6, 2012) ("NYCBA"), the Business Law Section of the American Bar Association (June 26, 2013) ("ABA Pre-Proposal") and Foley & Lardner (May 24, 2012) ("Foley").

1. Proposed Rule Amendment

We proposed to amend Rule 12g–1 to make clear that the definition of "accredited investor" in Securities Act Rule 501(a) applies in making determinations under Exchange Act Section 12(g)(1) and that the "accredited investor" determination must be made as of the last day of the fiscal year rather than at the time of the sale of the securities.[48] In proposing to use the Rule 501(a) definition, we stated our belief that applying the familiar concepts of the accredited investor definition in Rule 501(a) to the registration threshold in Section 12(g)(1) would facilitate compliance for issuers.[49] We also noted our concern that reliance on information previously provided by security holders in connection with the purchase or transfer of securities for an indefinite period into the future could result in the use of outdated information that may no longer be reliable.[50]

2. Comments on Proposed Rule Amendment

We received comments on the proposed approach from five commenters.[51] Four commenters supported the use of the Securities Act Rule 501(a) definition.[52] Two of these commenters requested that the Commission provide guidance on how to establish a reasonable belief of accredited investor status.[53] A number of commenters supported establishing a safe harbor for the accredited investor determination that permits an issuer to rely on previously obtained information relating to accredited investor status.[54] These commenters recommended various safe harbors that permit issuers to rely on: information obtained at the time securities were initially or most recently sold to that person;[55] an annual self-certification or affirmation;[56] and determinations made by certain third parties.[57] Another commenter provided a more limited recommendation that the Commission permit reliance on accredited investor status determinations made in offerings during the three months prior to fiscal year-end or on self-certification by investors if the offering occurred more than three months but less than twelve months prior to fiscal year-end.[58]

One commenter opposed a formal safe harbor out of concern it would become a *de facto* minimum standard and recommended instead that the Commission provide additional guidance.[59] Specifically, this commenter recommended that:

- an issuer should be able to rely on information previously provided by investors as indicative of their current accredited investor status, when there is a reasonable basis for doing so;
- an annual confirmation should only be necessary if there was reason to believe that an investor's status had changed;
- an issuer should be able to rely on certification from certain third parties; and
- an issuer should not be subject to enforcement if the basis was reasonable at the time the conclusion was reached.[60]

One commenter recommended that the Commission issue a separate rule or safe harbor with respect to private investment funds.[61] The commenter noted that private investment funds that rely on the exemption in Investment Company Act Section 3(c)(7)[62] ("3(c)(7) Funds") may have an unlimited number of investors that are "qualified purchasers," a significantly higher standard than "accredited investors." The commenter recommended a rule that permits 3(c)(7) Funds to continue to rely on their initial determination of a record holder's qualified purchaser and accredited investor status on a going forward basis without requiring additional annual diligence. In the alternative, the commenter recommended that the Commission provide a non-exclusive safe harbor that permits 3(c)(7) Funds to send an annual negative consent letter to record holders asking them to inform the issuer if their accredited investor status has changed and permits treatment of a non-response as confirmation of status.

Two commenters expressed concern about the timing of the determination and opposed requiring determination as of the last day of the fiscal year.[63] One of these commenters claimed that annual reconfirmation will be costly, will provide little investor protection and may cause issuers to sell to fewer investors.[64] This commenter recommended only requiring yearly recertification if there is a ready market for the securities and the securities are freely tradable.[65]

3. Final Rule Amendment

After considering the comments, we are adopting an amendment to Rule 12g–1 as proposed, providing that the term "accredited investor" for purposes of Section 12(g)(1) is as defined in Securities Act Rule 501(a).[66] Consistent with the proposal, the "accredited investor" determination for these purposes must be made as of the last day of the issuer's most recent fiscal year rather than at the time of the sale of the securities. Commenters supported use of the Securities Act Rule 501(a) definition.[67] Rule 501(a) provides that an accredited investor is any person who comes within one or more of the categories of investors specified therein, or whom the issuer reasonably believes comes within any such category. Whether the issuer has a reasonable belief depends on the particular facts and circumstances surrounding the determination. Under amended Rule 12g–1, an issuer will need to determine, based on facts and circumstances, whether prior information provides a basis for a reasonable belief that the security holder continues to be an accredited investor as of the last day of the fiscal year.[68]

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[48] Securities Act Rule 501(a) otherwise defines "accredited investor" as being determined at the time of the sale of the securities.

[49] *See* Proposing Release at Section II.C.

[50] *Id.*

[51] *See* letters from ABA, Alternative & Direct Investment Securities Association (Mar. 2, 2015) ("ADISA"), Investment Program Association (Mar. 2, 2015) ("IPA"), Securities Arbitration Clinic, Cardozo Law School (Mar. 2, 2015) ("Cardozo") and Managed Funds Association (Mar. 2, 2015) ("MFA").

[52] *See* letters from ABA, ADISA, Cardozo and MFA.

[53] *See* letters from ABA and ADISA. ABA recommended that the Commission provide guidance by rule or in the text of the release.

[54] *See* letters from ADISA, Milken Institute Center for Financial Markets (Mar. 2, 2015) ("CFM"), Cleary, Gottlieb, Steen & Hamilton LLP (Feb. 27, 2015) ("Cleary") and IPA. CFM suggested that a safe harbor would create certainty and predictability for issuers and investors. IPA recommended a safe harbor as an alternative to determination at time of the last sale and proposed that securities sold prior to the effective date of any rule should not be subject to reaffirmation of accredited investor status.

[55] *See* letters from ADISA and CFM.

[56] *See* letters from ADISA and IPA. CFM further recommended allowing an issuer to assume that an investor's status has not changed and to query investors "as needed" via a written communication.

[57] *See* letters from ADISA, Cleary and IPA. These commenters recommended permitting reliance on information from registered broker-dealers, registered investment advisers, licensed attorneys, or certified public accountants.

[58] *See* letter from Cleary.

[59] *See* letter from ABA.

[60] *See* letter from ABA. *See also* letter from IPA advocating against annual recertification, which noted that any future adjustments to the definition of accredited investor could affect an issuer's number of accredited investors. This could cause issuers to be required to register despite an issuer's efforts to sell only to an appropriately limited number of accredited and non-accredited investors at the time of the offer and sale. ABA recommended a presumption that a person continues to be an accredited investor under the revised definition to address concerns relating to future adjustments to the definition of accredited investor.

[61] *See* letter from MFA.

[62] 15 U.S.C. 80a–3(c)(7).

[63] *See* letters from ADISA and IPA. ADISA recommended permitting issuers to rely on information available at the time they made a judgment, rather than requiring issuers to update information as of the end of the fiscal year. IPA recommended that accredited investor status be determined at the time of last sale, not annually, and expressed concern regarding the administrative and reporting costs of determinations required as of the last day of the fiscal year.

[64] *See* letter from IPA. IPA cited an estimate of ongoing reporting costs under the Exchange Act of $650,000 annually. This commenter additionally noted that becoming an Exchange Act reporting company may be contrary to an issuer's business plan and against investors' economic interests.

[65] *See* letter from IPA. IPA suggested that most affected investors will not hold freely tradable securities, muting the benefits of public company reporting for those investors.

[66] Consideration of the use of the "accredited investor" definition in this context is distinct from other efforts to consider the definition. In December 2015, the staff issued a report addressing the "accredited investor" definition and providing certain recommendations for our consideration. *See Report on the Review of the Definition of Accredited Investor* (Dec. 18, 2015), available at *https://www.sec.gov/corpfin/reportspubs/special-studies/review-definition-of-accredited-investor-12-18-2015.pdf.*

Although some commenters requested that the Commission provide guidance on making the accredited investor determination in the Section 12(g) context or establish a safe harbor relating to the determination,[69] we have decided against doing so. Our rules do not currently provide a safe harbor for the reasonable belief determination made under Rule 501(a) for exempt offerings and we do not believe that the determinations required for Section 12(g) present a more compelling case for having such a safe harbor. Additionally, as one commenter noted, a safe harbor could become a *de facto* minimum standard.[70] We believe that requiring issuers to consider their particular facts and circumstances in establishing a reasonable basis for their determination provides issuers with appropriate flexibility for making the determination.[71]

As adopted, the accredited investor determination under Rule 12g–1 must be made as of the last day of the issuer's most recent fiscal year rather than at the time of the sale of the securities. Several commenters recommended that the Commission adopt rules providing that the determination need not be made at year-end.[72] We believe that a fiscal year-end determination date is appropriate because the Section 12(g)(1) requirement to register is triggered if the issuer meets the specified asset and held of record thresholds at the end of its fiscal year.

Other commenters recommended permitting an issuer to rely on previously obtained information relating to accredited investor status.[73] We continue to be concerned that permitting issuers to rely solely on previously obtained information, which in some cases could be years or decades old, could result in the use of outdated and unreliable information when making the determination. One commenter suggested that we permit issuers to rely on accredited investor determinations made in offerings during the three months prior to fiscal year-end or on self-certification by investors if the offering occurred more than three months but less than twelve months prior to fiscal year-end.[74] While such information could provide a reasonable basis for making a determination about accredited investor status as of the end of the fiscal year, for the reasons set forth above, we believe that issuers should consider their particular facts and circumstances before reaching such a conclusion and that the "reasonable belief" standard under Rule 501(a) provides issuers with a familiar context and appropriate flexibility in making such a determination.

III. Amendments to Exchange Act Rule 12g5–1

A. Statutory Requirement and Definition of "Employee Compensation Plan"

Exchange Act Section 12(g)(5), as amended by Section 502 of the JOBS Act, provides that the definition of "held of record" shall not include securities held by persons who received them pursuant to an "employee compensation plan" in transactions exempted from the registration requirements of Section 5 of the Securities Act. By its express terms, this new statutory exclusion applies solely for purposes of determining whether an issuer is required to register a class of equity securities under the Exchange Act and does not apply to a determination of whether such registration may be terminated or suspended.[75] The provision, which is substantially broader than the Commission's existing rules exempting compensatory employee stock options from Section 12(g) registration,[76] does not define the term "employee compensation plan."

Section 503 of the JOBS Act instructs the Commission to amend the definition of "held of record" to implement the amendment in Section 502 and to adopt a safe harbor that issuers can use when determining whether holders of their securities received them pursuant to an employee compensation plan in transactions exempted from the registration requirements of Section 5 of the Securities Act.

1. Proposed Rule Amendment

We did not propose to define the term "employee compensation plan." Instead, we proposed to revise the definition of "held of record" and to additionally establish a non-exclusive safe harbor that relies on the current definition of "compensatory benefit plan" in Rule 701 and the conditions in Rule 701(c).

2. Comments on Proposed Rule Amendment

We received comments from two commenters generally supportive of the proposed amendment.[77] One of those commenters specifically supported our determination not to create a new definition of the term "employee compensation plan."[78] This commenter suggested that application in a Section 12(g) context of the familiar concepts applied by an issuer in connection with its exempt issuances of compensatory equity securities under Securities Act Rule 701 would facilitate compliance by streamlining the issuer's learning curve and simplifying recordkeeping.

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[67] *See* letters from ABA, ADISA, Cardozo and MFA.

[68] If after the issuer has made its determination as of the end of the fiscal year, it is subsequently determined that an investor did not, in fact, come within one of the accredited investor categories, the issuer may rely on that determination for that fiscal year if it had a reasonable belief at the time the determination was made.

[69] *See* letters from ABA, ADISA, CFM, Cleary and MFA.

[70] *See* letter from ABA.

[71] One commenter requested that the Commission establish a separate safe harbor or rule with respect to private investment funds. *See* letter from MFA. We are declining to provide specific relief to private investment funds for reasons similar to those discussed for issuers generally. We believe that a standard where issuers, including private investment funds, consider their particular facts and circumstances in establishing a reasonable basis for believing that a security holder is an accredited investor is the most appropriate standard to apply at this time.

[72] *See* letters from ADISA and IPA.

[73] *See* letters from ABA, CFM, Cleary and MFA.

[74] *See* letter from Cleary.

[75] The statutory exclusion in Section 12(g)(5) specifically refers to Exchange Act Section 12(g)(1), which relates to when an issuer must register its securities with the Commission.

[76] Exchange Act Rule 12h–1(f) [17 CFR 240.12h–1(f)] provides non-reporting issuers with an exemption from Section 12(g) registration for stock options issued under written compensatory stock option plans under certain conditions. Exchange Act Rule 12h–1(g) [17 CFR 240.12h-1(g)] provides reporting issuers a similar exemption for such stock options. The exemptions provide specific eligibility requirements and are limited to options issued pursuant to a written compensatory stock option plan. *See Exemption of Compensatory Stock Options from Registration Under Section 12(g) of the Securities Exchange Act of 1934,* Release No. 34–56887 (Dec. 3, 2007) [72 FR 69554 (Dec. 7, 2007)].

[77] *See* letters from ABA and ADISA.

[78] *See* letter from ABA.

3. Final Rule Amendment

After considering the comments, we are adopting an amendment to Rule 12g5–1 to revise the definition of "held of record," and establish a non-exclusive safe harbor. By not defining the term "employee compensation plan," and providing for a non-exclusive safe harbor, we believe issuers will have appropriate flexibility to make a principles-based determination about securities received as employee compensation when determining their holders of record under Section 12(g)(5), as well as the added certainty of a safe harbor. We further believe that developing a new definition for "employee compensation plan" could result in needless complexity and create potential conflicts with the current definitions of "compensatory benefit plan" and "employee benefit plan." [79] Finally, we note that by conditioning the new exclusion from "held of record" upon the securities being received pursuant to an employee compensation plan in transactions exempted from the registration requirements of Section 5 of the Securities Act, Section 502 of the JOBS Act uses Securities Act concepts to identify persons that an issuer may exclude from its determination of the number of holders of record under Section 12(g)(1) of the Exchange Act. Because this provision of the JOBS Act includes concepts from both the Securities Act and Exchange Act,[80] we believe that it will facilitate compliance if the terminology used in the new safe harbor in Exchange Act Rule 12g5–1(a)(8)(ii) is consistent with the terminology used in our Securities Act rules.

B. Definition of "Held of Record"

Section 503 of the JOBS Act directed the Commission to revise the definition of "held of record" pursuant to Section 12(g)(5) to provide that securities held by persons who received them pursuant to an employee compensation plan in transactions exempted from the registration requirements of Section 5 of the Securities Act may be excluded when calculating the number of holders of record of a class of equity securities for purposes of determining the issuer's registration obligation under Section 12(g)(1). We received pre-proposal comments addressing issues about the scope of the definition. One commenter recommended that securities issued in a subsequent transaction (including a business combination) that is exempt from, or otherwise is not subject to, the registration requirements of Section 5 to eligible employees, former employees and other covered persons in exchange for securities covered by the Section 12(g)(5) compensatory plan securities carve-out also should be excluded.[81] The same commenter further recommended that securities issued in unregistered transactions based on the "no sale" theory[82] should be included within the definition of "transactions exempt from Section 5."

1. Proposed Rule Amendment

We proposed to amend the definition of "held of record" to provide that when determining whether an issuer is required to register a class of equity securities with the Commission pursuant to Exchange Act Section 12(g)(1) an issuer may exclude securities that are either:

- held by persons who received the securities pursuant to an employee compensation plan in transactions exempt from the registration requirements of Section 5 of the Securities Act;
- held by persons who received the securities pursuant to an employee compensation plan in transactions that did not involve a sale within the meaning of Section 2(a)(3) of the Securities Act; or
- held by persons eligible to receive securities from the issuer pursuant to Securities Act Rule 701(c) who received the securities in a transaction exempt from the registration requirements of Section 5 of the Securities Act in exchange for securities excludable under proposed Rule 12g5–1(a)(7).

Section 502 of the JOBS Act refers specifically to "transactions exempted" from the Securities Act Section 5 registration requirements. A number of issuers, however, issue securities to employees without Securities Act registration on the basis that the issuance is not a sale under Section 2(a)(3) of the Securities Act and therefore does not trigger the registration requirement of Securities Act Section 5, which applies only to the offer and sale of securities.[83] While securities issued to employees in transactions that do not involve a sale under Section 2(a)(3) are not technically "transactions exempted from the registration requirements of section 5," they are similar to other compensatory issuances to employees in exempt transactions in that the issuer provides the awards to employees for a compensatory purpose. We therefore proposed to exclude such "no sale" issuances from the definition of "held of record" in Rule 12g5–1 for purposes of determining an issuer's obligation to register a class of securities under the Exchange Act.

Additionally, we proposed to permit an issuer to exclude securities of holders who are persons eligible to receive securities from the issuer pursuant to Rule 701(c) and who acquired the securities in exchange for securities excludable under the proposed definition. The proposed exclusion was intended to facilitate the ability of an issuer to conduct restructurings, business combinations and similar transactions that are exempt from Securities Act registration so that if the securities being surrendered in such a transaction would not have been counted under the proposed definition of "held of record," the securities issued in the exchange also would not be counted under this definition.[84] The securities issued in the exchange would be deemed to have a compensatory purpose because they would replace other securities previously issued pursuant to an employee compensation plan. We believed such an approach would be consistent with the intent of Section 502 of the JOBS Act and would provide issuers with appropriate flexibility to conduct certain business combinations and similar transactions.

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[79] *See Rule 701—Exempt Offerings Pursuant to Compensatory Arrangements,* Release No. 33–7645 (Feb. 25, 1999) [64 FR 11095 (Mar. 8, 1999)] (the "1999 Rule 701 Release"), and *Registration of Securities on Form S–8,* Release No. 33–7646 (Feb. 25, 1999) [64 FR 11103 (Mar. 8, 1999)] (the "1999 Form S–8 Release").

[80] This provision of the JOBS Act relies on concepts from both the Securities Act and the Exchange Act by establishing that certain securities received pursuant to an employee compensation plan in transactions exempted from the registration requirements of Section 5 of the Securities Act may be excluded when determining whether an issuer is required to register under Section 12(g) of the Exchange Act.

[81] *See* letter from ABA Pre-Proposal.

[82] The "no sale" theory relates to the issuance of compensatory grants made by employers to broad groups of employees pursuant to broad-based stock bonus plans without Securities Act registration under the theory that the awards are not an offer or sale of securities under Section 2(a)(3) of the Securities Act [15 U.S.C. 77b(a)(3)]. *See Employee Benefit Plans; Interpretations of Statute,* Release No. 33–6188 (Feb. 1, 1980) [45 FR 8960 (Feb. 11, 1980)] at Section II.A.5.d; *Employee Benefit Plans,* Release No. 33–6281 (Jan. 15, 1981) [46 FR 8446 (Jan. 27, 1981)] at Section III. Many issuers rely on the "no sale" theory when making such awards to employees where no consideration—and hence no "value"—is received by the issuer in return. The staff has not objected to these issuances in a series of no-action letters. *See, e.g.,* no-action letter to *Verint Systems Inc.* (May 24, 2007).

[83] *See id.*

[84] As proposed and consistent with Rule 701(c), securities held of record by former employees would be excluded when determining the securities held of record only if the employees were employed by or providing services to the surviving issuer at the time the exchange securities were offered.

2. Comments on Proposed Rule Amendment

We received comments on the proposed amendment from two commenters, both generally supporting the amendment.[85] One commenter supported the proposed amendment to the definition of "held of record" to implement JOBS Act Section 503, but recommended that the Commission clarify and extend the scope of the proposed exclusion for securities received in exchange for excludable securities.[86] The commenter recommended that the Commission revise the exclusion for employee compensation plan securities acquired through a business combination to encompass securities that are "exempt from, or not subject to, the registration requirements of Section 5 of the Securities Act." The commenter noted that the proposed language, if construed literally, may not apply to exempt securities under Section 3 of the Securities Act, such as securities issued under Section 3(a)(9) (in connection with exchange offers), Regulation A or Rule 504 or 505 of Regulation D, because those exemptions are securities-based rather than transaction-based. Finally, the commenter noted that business combinations do not always involve an exchange and suggested additional clarification that the rule would apply to securities received "in exchange for, in substitution for or upon conversion or exercise of" the original securities.

This commenter additionally recommended that the Commission expand the exclusion for securities issued in business combinations and similar transactions that replace securities previously issued pursuant to an employee compensation plan to include former employees, directors, general partners, trustees, officers, or consultants and advisors who were employed by, or providing services to, a predecessor of the issuer or a company acquired in a business combination. The commenter expressed concern that denying the exclusion to former employees could inhibit issuers from entering into business combination transactions.

3. Final Rule Amendment

After considering the comments, we are adopting Exchange Act Rule 12g5–1(a)(8)(i) with the clarifications and changes detailed below.[87] We are amending the definition of "held of record" to provide that when determining whether an issuer is required to register a class of equity securities with the Commission pursuant to Exchange Act Section 12(g)(1) an issuer may exclude securities that are:

- Held by persons who received the securities pursuant to an employee compensation plan in transactions exempt from, or not subject to, the registration requirements of Section 5 of the Securities Act; or
- held by persons who received the securities in a transaction exempt from, or not subject to, the registration requirements of Section 5 of the Securities Act from this issuer, a predecessor of the issuer or an acquired company in substitution or exchange for excludable securities under Exchange Act Rule 12g5–1(a)(8)(i)(A), as long as the persons were eligible to receive securities pursuant to Rule 701(c) at the time the excludable securities were originally issued to them.

Consistent with one commenter's suggestion,[88] we are revising the language in new Exchange Act Rule 12g5–1(a)(8)(i)(A) to encompass securities received in transactions exempt from, or not subject to, the registration requirements of Section 5. Such transactions include transactions that did not involve a sale of securities within the meaning of Section 2(a)(3) of the Securities Act, as well as transactions involving exempt securities, such as sales of securities made pursuant to Section 3 of the Securities Act. As we indicated in the Proposing Release, while securities issued to employees in transactions that do not involve a sale under Section 2(a)(3) are not technically "transactions exempted from the registration requirements of Section 5," they are similar to other compensatory issuances to employees in exempt transactions in that the issuer provides the awards to employees for a compensatory purpose. We believe it is consistent with the statutory relief to also exclude from the definition of "held of record" in Rule 12g5–1 exempt securities issued to employees pursuant to an employee compensation plan. These exempt securities are similarly issued to employees for compensatory purposes and their issuance does not require registration under the Securities Act.

We are adopting new Exchange Act Rule 12g5–1(a)(8)(i)(B) to provide relief in the context of business combinations. We are clarifying and expanding the proposed relief to encompass securities held by former employees of the issuer or its predecessors. In response to a commenter's concern that the term "in exchange for" is not broad enough to capture all of the ways in which a person may receive new securities in place of existing securities held prior to a business combination, we have revised the language by using the phrase "in substitution or exchange for" to cover various methods of how those securities may be received in place of the existing securities, such as upon conversion or exercise of such securities. In response to a commenter's concerns,[89] we are revising proposed Rule 12g5–1(a)(8)(i)(B) to also permit securities to be excluded if they were received by former employees in an exempt transaction in substitution or exchange for excludable securities, where the former employees were eligible under Rule 701(c) to receive the original securities at the time of issuance. Under the exemption as proposed, securities received in such an exchange by former employees of an issuer and employees of an acquired issuer or the target company in a business combination would not have been excludable. Requiring issuers to count those securities for Exchange Act registration purposes could, as the commenter noted, inhibit issuers from entering into economically beneficial business combinations. Such former employees of the issuer, and employees of a predecessor of the issuer or an acquired company, will have received the original securities pursuant to an employee compensation plan in a transaction exempt from, or not subject to, the registration requirements of Section 5 of the Securities Act. We therefore believe it is appropriate to exclude the securities received by these former employees[90] in such an exchange when determining whether an issuer is required to register under Section 12(g)(1).

C. Non-Exclusive Safe Harbor for Determining Holders of Record

Section 503 of the JOBS Act directed the Commission to establish a safe harbor in Rule 12g5–1 that issuers can rely on when determining if securities held by persons who received them pursuant to an employee compensation plan in transactions exempted from the registration requirements of Section 5 of the Securities Act may be excluded when calculating the number of holders of record of a class of equity securities for purposes of determining the issuer's registration obligation under Section 12(g)(1). One pre-proposal commenter recommended that the Commission expressly provide a non-exclusive safe harbor akin to the Securities Act Rule 506 safe harbor under Securities Act Section 4(a)(2).[91] This commenter recommended that the safe harbor provide that an issuer may treat an issuance of securities as exempt from Securities Act registration for purposes of Section 12(g)(5) if that issuer had a reasonable belief that the exemption was available at the time the securities were issued.[92]

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[85] *See* letters from ABA and ADISA.

[86] *See* letter from ABA.

[87] As part of the amendments to Regulation A, we adopted a new Exchange Act Rule 12g5–1(a)(7) providing a conditional exemption to the definition of "held of record" for securities issued in Tier 2 Regulation A offerings. *Amendments to Regulation A,* Rel. No. 33–9741 (Mar. 25, 2015) [80 FR 21805 (Apr. 20, 2015)]. We proposed to use Rule 12g5–1(a)(7) for the exemption and safe harbor under the definition of "held of record" for certain employee compensation plan securities in the Proposing Release. Because Rule 12g5–1(a)(7) has been adopted in relation to Regulation A, we are adopting the proposed exemption and safe harbor as Exchange Act Rule 12g5–1(a)(8).

[88] *See* letter from ABA.

[89] *Id.*

[90] Rule 701(c) provides appropriate limitations on who may qualify as an employee, former employee, or permitted family member transferee. See discussion in Section III.C.3.a.

1. Proposed Rule Amendment

We proposed a non-exclusive safe harbor that would provide that a person will be deemed to have received the securities pursuant to an employee compensation plan if such person received them pursuant to a compensatory benefit plan in transactions that met the conditions of Securities Act Rule 701(c).

2. Comments on Proposed Rule Amendment

We received comments on the proposed amendment from two commenters, both generally supporting the amendment.[93] One commenter, while generally supportive of the rule and safe harbor, expressed concern that an issuer's ability to rely on the safe harbor was conditioned on the issuer's ability to demonstrate compliance with all of the express requirements of an exemption, placing undue emphasis on technical aspects of the exemption that should not serve as the basis for determining whether an issuer should be required to register under Section 12(g).[94] This commenter suggested that Section 503 of the JOBS Act should be read to mandate that the safe harbor provide certainty with respect to the exempt offering condition of JOBS Act Section 502 and that if the safe harbor requires an issuer to establish annually that each issuance of exempt equity securities satisfied an available Securities Act exemption, then the safe harbor would impose a significant ongoing burden on the issuer. The commenter recommended revising the safe harbor so that, solely for purposes of Exchange Act Section 12(g), the original issuance would be deemed to have satisfied the Securities Act exemption condition if the conditions of Securities Act Rule 701(c) are satisfied at the end of the fiscal year.[95]

Two commenters made recommendations that the Commission provide more guidance on the application of Securities Act Rule 701(c), or modify the application of Rule 701(c) in the Section 12(g) context.[96] One commenter recommended that there be no limit on the categories of persons who may receive securities pursuant to an employee compensation plan for purposes of the safe harbor.[97] Another commenter recommended expanding the provisions of Securities Act Rule 701(c) to exempt any consultants and advisors, instead of maintaining the limitation in Rule 701(c) to consultants and advisors who are natural persons.[98] This commenter also recommended that the Commission explicitly provide that Rule 701(c) extends to family members who acquire equity securities initially issued pursuant to a compensatory benefit plan from an employee (or former employee) by gift or domestic relations order, or upon an employee's death or disability, as well as to the executor or guardian of the employee, former employee, or family member who acquires the securities upon such person's death or disability.

3. Final Rule Amendment and Interpretation

After considering the comments, we are adopting the proposed amendment to Exchange Act Rule 12g5–1(a)(8) with the additions and clarifications detailed below. We are adopting a non-exclusive safe harbor.[99] The safe harbor provides that:

- an issuer may deem a person to have received the securities pursuant to an employee compensation plan if such plan and the person who received the securities pursuant to the plan met the plan and participant conditions of Securities Act Rule 701(c); and
- an issuer may, solely for the purposes of Section 12(g), deem the securities to have been issued in a transaction exempt from, or not subject to, the registration requirements of Section 5 of the Securities Act if the issuer had a reasonable belief at the time of the issuance that the securities were issued in such a transaction.

a. Employee Compensation Plan

We believe that using the conditions of Rule 701(c) to structure the employee compensation plan safe harbor for the determination that a person received the securities pursuant to an employee compensation plan allows issuers to apply well understood principles of an existing Securities Act exemption to the new Exchange Act registration determination created by the JOBS Act. We believe application in a Section 12(g) context of the familiar concepts applied in connection with the issuance of compensatory equity securities under Securities Act Rule 701 will facilitate compliance and simplify recordkeeping.

Rule 701 exempts from Securities Act registration offers and sales of securities pursuant to certain compensatory benefit plans and contracts relating to compensation. Rule 701(c) limits this exemption to offers and sales of securities under a written compensatory benefit plan established by the issuer, its parents, its majority-owned subsidiaries or majority-owned subsidiaries of the issuer's parent, for the participation of their employees, directors, general partners, trustees, officers, or consultants and advisors.[100]

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[91] *See* letter from ABA Pre-Proposal recommending that the Commission provide "that the safe harbor(s) is *not* the exclusive means by which an issuer may comply with the 'compensatory plan carve-out' provisions of Section 12(g)(5)." This commenter suggested that "failure to satisfy all conditions to reliance on the safe harbor(s) should not preclude reliance on the statutory carve-out itself."

[92] *See* letter from ABA Pre-Proposal.

[93] *See* letters from ABA and ADISA.

[94] *See* letter from ABA.

[95] *Id.*

[96] *See* letters from ABA and ADISA.

[97] *See* letter from ADISA.

[98] *See* letter from ABA.

[99] Failure to satisfy all of the conditions of the non-exclusive safe harbor would not preclude reliance on Section 12(g)(5) or other provisions of the rule.

[100] Securities Act Rule 701(c) exempts offers and sales of securities (including plan interests and guarantees pursuant to Rule 701(d)(2)(ii)) under a written compensatory benefit plan (or written compensation contract) established by the issuer, its parents, its majority-owned subsidiaries or majority-owned subsidiaries of the issuer's parent, for the participation of their employees, directors, general partners, trustees (where the issuer is a business trust), officers, or consultants and advisors, and their family members who acquire such securities from such persons through gifts or domestic relations orders. This section exempts offers and sales to former employees, directors, general partners, trustees, officers, consultants and advisors only if such persons were employed by or providing services to the issuer at the time the securities were offered. In addition, the term "employee" includes insurance agents who are exclusive agents of the issuer, its subsidiaries or parents, or who derive more than 50% of their annual income from those entities. As explained in the 1999 Rule 701 Release at Section II.D, Rule 701 is also available to persons with a *de facto* employment relationship with the issuer. Such a relationship would exist where a person not employed by the issuer provides the issuer services that traditionally are performed by an employee and the compensation paid for those services is the primary source of the person's earned income.

Rule 701(c)(1) sets forth special requirements for consultants and advisors [101] and Rule 701(c)(3) defines eligible family members.[102]

The safe harbor we are adopting today is available for the plan participants enumerated in Rule 701(c), including employees, directors, general partners, trustees, officers and certain consultants and advisors.[103] The safe harbor also is available for permitted family member transferees with respect to securities issued pursuant to a plan that are acquired by gift or domestic relations order from plan participants, or such securities acquired by permitted family member transferees in connection with options transferred to them by the plan participant through gifts or domestic relations orders.[104] Because the safe harbor is limited to holders who are persons specified in Rule 701(c), once these persons subsequently transfer the securities to holders not specified in Rule 701(c), whether or not for value, the securities must be counted as held of record by the transferee for purposes of determining whether the issuer is subject to the registration and reporting requirements of Exchange Act Section 12(g)(1).

An issuer may rely on the safe harbor when determining the holders of securities issued in reliance on Securities Act Rule 701, as well as holders of securities issued in transactions otherwise exempted from, or not subject to, the registration requirements of the Securities Act that satisfy the conditions of Rule 701(c), even if all the other conditions of Rule 701, such as issuer eligibility in Rule 701(b)(1), the volume limitations in Rule 701(d) or the disclosure delivery provisions in Rule 701(e), are not met. Thus, the safe harbor is available for holders of securities received in other employee compensation plan transactions exempted from, or not subject to, the registration requirements of Section 5 of the Securities Act, such as securities issued in reliance on Securities Act Section 4(a)(2), Regulation A, Regulation D, or Regulation S under the Securities Act, that also meet the conditions of Rule 701(c).

b. Securities Issued in Exempt Transactions

In response to comments, we are adding a provision to the safe harbor relating to the determination that the securities were issued in a transaction exempt from, or not subject to, the registration requirements of Section 5 of the Securities Act. The addition to the safe harbor provides that, solely for purposes of Section 12(g) of the Exchange Act, an issuer may deem securities to have been exempt from, or not subject to, the registration requirements of Section 5 of the Securities Act if the issuer had a reasonable belief at the time of issuance that the securities were issued in a transaction that was exempt from, or not subject to, the registration requirements of Section 5.

While one commenter recommended that the safe harbor should deem the securities qualified for the Securities Act exemption if the conditions of Securities Act Rule 701(c) were met as of the end of the fiscal year,[105] we believe that such a safe harbor would go too far and negate the requirement that the securities have been issued in a transaction exempt from, or not subject to, the registration requirements of Section 5 of the Securities Act at the time of issuance. Instead, the safe harbor provides issuers with relief from the burden of establishing that earlier issuances of securities satisfied an appropriate exemption on an annual basis provided it had a reasonable belief that it had complied with the appropriate registration requirements or the conditions of an applicable exemption at the time of issuance.

c. Interpretative Guidance Relating to Acquisitions by Family Members

One commenter recommended that the Commission provide guidance regarding the application of Rule 701 to certain equity securities initially issued pursuant to a compensatory benefit plan acquired from an employee (or former employee) by gift or domestic relations order, or upon an employee's (or former employee's) death or disability.[106] In light of the nature of such transactions, family members (as defined in Rule 701(c)) who receive the equity securities as a result of the employee's (or former employee's) gift, domestic relations order, or death are also considered as persons who received "the securities pursuant to an employee compensation plan" for purposes of Rule 12g5–1(a)(8).[107]

D. Foreign Private Issuers

1. Proposed Rule Amendments

While "foreign private issuers" [108] would be able to rely on Exchange Act

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[101] The Commission adopted amendments to Form S–8 and the Rule 405 definition of "employee benefit plan" that made Form S–8 available for the issuance of securities to consultants or advisors only if: They are natural persons; they provide *bona fide* services to the registrant; and the services are not in connection with the offer or sale of securities in a capital-raising transaction, and do not directly or indirectly promote or maintain a market for the registrant's securities. *See* 1999 Form S–8 Release and 1999 Rule 701 Release. Rule 701(c)(1) applies the same limitations regarding consultants and advisors as those provided in Form S–8 and the Rule 405 definition of "employee benefit plan."

[102] Rule 701 is available for the exercise of employee benefit plan options by an employee's family member who has acquired the options from the employee through a gift or a domestic relations order. As defined in Exchange Act Rule 701(c)(3) [17 CFR 230.701(c)(3)], for this purpose, "family member" includes any child, stepchild, grandchild, parent, stepparent, grandparent, spouse, former spouse, sibling, niece, nephew, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law, including adoptive relationships, any person sharing the employee's household (other than a tenant or employee), a trust in which these persons have more than 50% of the beneficial interest, a foundation in which these persons (or the employee) control the management of assets, and any other entity in which these persons (or the employee) own more than 50% of the voting interests.

[103] Unlike traditional employees, consultants and advisors typically provide their services to multiple clients rather than to the same issuer on a dedicated basis. This distinction may cause them to be less likely to hold the securities they receive as compensation and more likely to sell them. As a result the Commission limited the consultants and advisors eligible to rely on the exemption. *See* 1999 Rule 701 Release at Section II.D. We believe that in light of the Rule 701 restrictions applicable to consultants and advisors, the compensatory nature of the transactions justifies treating consultants and advisors who are eligible to receive securities in compensatory transactions that satisfy the conditions of Rule 701(c) as persons who receive securities pursuant to an employee compensation plan for purposes of the Rule 12g5–1 safe harbor. Furthermore, since the securities would no longer be eligible for the exclusion under the safe harbor following their transfer, we believe the potential for abuse would be limited. However, in spite of one commenter's recommendation (*see* letter from ABA), we see no reason to expand the scope of eligible consultants and advisors under Section 12(g) or Rule 701, which the Commission narrowed in 1999 in order to address abuses in the use of Form S–8 and Rule 701. *See Registration of Securities on Form S–8,* Release No. 33–7646 (Feb. 25, 1999) [64 FR 11103 (Mar. 8, 1999)]; *Rule 701—Exempt Offerings Pursuant to Compensatory Arrangements,* Release No. 33–7645 (Feb 25, 1999) [64 FR 11095 (Mar. 8, 1999)].

[104] *See Rule 701—Exempt Offerings Pursuant to Compensatory Arrangements,* Release No. 33–7511 (Feb. 27, 1998) [63 FR 10785 (Mar. 5, 1998)] at Section III.E.4. Including family member transferees in the safe harbor is consistent with the approach in Rule 701(c), which provides an exemption to family member transferees in connection with stock options because of their common economic interest and the non-capital raising nature of the transactions.

[105] *See* letter from ABA.

[106] *See* letter from ABA.

[107] In general we understand that guardians or members of a committee for incompetent former employees, or similar persons duly authorized by law to administer the assets of former employees would administer the assets for the benefit of the former employee and title would not have transferred to these agents. In such circumstances, the securities would meet the conditions of Rule 701(c) for purposes of determining the holders of record.

[108] *See* Exchange Act Rule 3b–4(c) [17 CFR 240.3b–4(c)]. A foreign private issuer is any foreign issuer other than a foreign government, except for an issuer that (1) has more than 50% of its

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Rule 12g5–1(a)(8) when making their determination of the number of U.S. resident holders under Exchange Act Rule 12g3–2(a), we proposed to amend Exchange Act Rule 3b–4 to clarify that securities held by employees must continue to be counted for the purpose of determining the percentage of the issuer's outstanding securities held by U.S. residents, and thus for determining whether an issuer qualifies as a foreign private issuer. We also proposed to amend the definition of "foreign private issuer" under Securities Act Rule 405 to reinsert an omitted instruction but with a proposed revision, identical to that proposed under Exchange Act Rule 3b–4, clarifying that securities held by employees must continue to be counted for the purposes of determining the percentage of the issuer's outstanding securities held by U.S. residents and foreign private issuer status under the Securities Act.[109]

2. Comments on Proposed Rule Amendments

We received comments on the proposed amendments from one commenter, who supported the proposed amendments relating to foreign private issuers.[110]

3. Final Rule Amendments

After considering the comments, we are adopting the amendments substantially as proposed. Under the rules we are adopting, foreign private issuers may rely on Rule 12g5–1(a)(8) when making their determination of the number of U.S. resident holders under Exchange Act Rule 12g3–2(a).[111] Under Rule 12g3–2(a), foreign private issuers that meet the asset and shareholder threshold for registration under Section 12(g) are exempt from registering any class of securities under that section if the class of securities is held by fewer than 300 holders resident in the United States.[112] For purposes of determining whether this threshold is met, Rule 12g3–2(a)(1) specifies that the method shall be as provided in Exchange Act Rule 12g5–1, except that securities held of record by brokers, dealers, banks and nominees for the accounts of customers resident in the United States shall be counted as held by the number of separate accounts for which the securities are held.[113] Because the rule directs issuers to the definition of "held of record" in Rule 12g5–1, the statutory changes to Section 12(g)(5) as well as the amendment to Rule 12g5–1 adopted today also apply to the determination of a foreign private issuer's U.S. resident holders for the purposes of the Rule 12g3–2(a) analysis.[114]

IV. Economic Analysis

Title V and Title VI of the JOBS Act increased the registration thresholds for issuers, amended the definition of "held of record" to exclude securities issued pursuant to employee compensation plans and increased the thresholds for termination of registration and suspension of reporting under the Exchange Act for banks and bank holding companies. The FAST Act similarly increased the thresholds for registration, termination of registration and suspension of reporting under the Exchange Act for savings and loan holding companies. The Commission is adopting amendments to implement Title V and Title VI of the JOBS Act and Title LXXXV of the FAST Act.

In adopting rules or amendments, we are mindful of the costs imposed by and the benefits obtained from our rules. The discussion below attempts to address the economic effects of the amendments, including the likely costs and benefits of the amendments as well as the effect of the amendments on efficiency, competition and capital formation.[115] Some of the costs and benefits stem from the statutory mandates of Title V and Title VI of the JOBS Act and Title LXXXV of the FAST Act, while others are affected by the discretion we exercise in revising our rules to reflect this mandate. For purposes of this economic analysis, we address the benefits and costs resulting from the mandatory statutory provisions and our exercise of discretion together because the two types of costs and benefits are not readily separable. We also analyze the benefits and costs of significant alternatives to the amendments that were suggested by commenters and that we considered on our own accord.

A. Baseline

The baseline for our economic analysis of the amendments, including the baseline for our consideration of the effects on efficiency, competition and capital formation, is the state of the market as well as market practices prior to enactment of the JOBS Act and the FAST Act. Prior to the JOBS Act, issuers were required to register a class of their equity securities with the Commission upon reaching 500 holders of record and total assets of $10 million[116] and were allowed to terminate registration or suspend the duty to file periodic and current reports with the Commission when the number of holders of record had fallen below 300, or below 500 and total assets had not exceeded $10 million on the last day of each of the issuer's three most recent fiscal years. In addition, Exchange Act Rules 12h–1(f) and 12h–1(g) permitted issuers to exclude stock options issued under written compensatory benefit plans under certain conditions from the registration requirements of Section 12(g).

The JOBS Act raised the thresholds at which an issuer is required to register a class of equity securities with the Commission pursuant to Section 12(g) and provided that persons holding certain employee compensation plan

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outstanding voting securities held of record by U.S. residents and (2) any of the following: (i) A majority of its officers and directors are citizens or residents of the United States; (ii) more than 50% of its assets are located in the United States; or (iii) its business is principally administered in the United States.

[109] 17 CFR 230.405. The definition of "foreign private issuer" under the Securities Act is intended to be the same as the definition under Exchange Act Rule 3b–4.

[110] *See* letter from ABA.

[111] 17 CFR 240.12g3–2(a).

[112] *Id.*

[113] The amendment to Rule 12g5–1 is limited to determinations under Section 12(g). The definition of "foreign private issuer" in Exchange Act Rule 3b–4 contains a cross-reference to Rule 12g3–2(a) for purposes of calculating record ownership in determining whether more than 50% of an issuer's outstanding voting securities are directly or indirectly held by residents of the United States. In contrast to the approach in Rule 12g3–2(a), Rule 3b–4 clarifies that securities held by employees must continue to be counted for the purpose of determining the percentage of the issuer's outstanding securities held by U.S. residents, and thus for determining whether an issuer qualifies as a foreign private issuer. *See* Instruction to paragraph (c)(1) of Rule 3b–4. We are revising the Instruction to paragraph (c)(1)A.2. from the proposal to clarify that all of Rule 12g5–1(a)(8) does not apply for purposes of making a determination under Rule 405 as to foreign private issuer status.

[114] The definition of "foreign private issuer" under the Securities Act, which is found in Securities Act Rule 405, is the same as the definition under Exchange Act Rule 3b–4. We are similarly amending the foreign private issuer definition under Rule 405 to reinsert an omitted instruction with an identical revision to that in Rule 3b–4, clarifying that securities held by employees must continue to be counted for the purposes of determining the percentage of the issuer's outstanding securities held by U.S. residents and foreign private issuer status under the Securities Act.

[115] Section 23(a)(2) of the Exchange Act [17 U.S.C. 78w(a)(2)] requires the Commission, when making rules under the Exchange Act, to consider the impact that the rules would have on competition, and prohibits the Commission from adopting any rule that would impose a burden on competition not necessary or appropriate in furtherance of the Exchange Act. 15 U.S.C. 78w(a). Further, Section 2(b) of the Securities Act [15 U.S.C. 77b(b)] and Section 3(f) of the Exchange Act [17 U.S.C. 78c(f)] require the Commission, when engaging in rulemaking where it is required to consider or determine whether an action is necessary or appropriate in the public interest, to consider, in addition to the protection of investors, whether the action will promote efficiency, competition and capital formation.

[116] *See supra* note 31.

securities need not be counted when determining whether an issuer is required to register. The JOBS Act also raised the thresholds at which an issuer that is either a bank or a bank holding company is permitted to terminate registration or suspend reporting obligations with the Commission. These statutory changes were effective immediately upon signing of the JOBS Act. As a result, some banks and bank holding companies were newly eligible to terminate registration or suspend reporting. As of December 31, 2015, we estimate that approximately 103 such institutions have elected to do so.[117] We estimate that there are approximately 486 banks and bank holding companies that currently report to the Commission,[118] of which some may be eligible to terminate registration under the JOBS Act but have elected to continue reporting.

Subsequent to the JOBS Act, the FAST Act raised the thresholds at which savings and loan holding companies are required to register and permitted to terminate registration or suspend reporting obligations to the same thresholds as apply to banks and bank holding companies. These statutory changes were effective immediately upon signing of the FAST Act. We estimate that, as of December 31, 2015, there are approximately 64 savings and loan holding companies that currently report to the Commission, approximately 28 of which are eligible to terminate registration or suspend reporting under the amendments.[119]

We are amending specified Exchange Act rules to reflect the new, higher threshold for banks, savings and loan holding companies and bank holding companies under Section 12(g)(4) and Section 15(d)(1). For those banks, savings and loan holding companies and bank holding companies that are eligible to terminate registration under Section 12(g), the amendments will provide the same procedural accommodations available to other issuers under current rules by permitting these institutions to suspend their reporting obligations immediately upon the filing of a certification on Form 15 with the Commission.

In addition, the amendments apply the definition of "accredited investor" in Securities Act Rule 501(a) in making determinations under Exchange Act Section 12(g)(1), revise the definition of "held of record" in Rule 12g5–1, and establish a non-exclusive safe harbor for issuers to rely on when determining whether securities were received pursuant to an employee compensation plan in transactions exempt from, or not subject to, the registration requirements of Section 5 of the Securities Act. The non-exclusive safe harbor, as adopted, permits an issuer to rely on the definition of "compensatory benefit plan" in Securities Act Rule 701 and the conditions in Securities Act Rule 701(c) in determining whether a person has received securities pursuant to an employee compensation plan. It also permits an issuer to rely on a reasonable belief at the time of issuance that the securities were issued in a transaction exempt from, or not subject to, the registration requirements of Section 5.

We considered alternative definitions of "employee compensation plan." We also considered whether to provide additional guidance with respect to the determination of accredited investor status when establishing the number of holders of record. These decisions may affect how a non-reporting issuer counts its holders of record for the purpose of the registration thresholds under the Exchange Act; hence, they could affect whether an issuer becomes subject to Exchange Act reporting. However, due to limited availability of shareholder information on these non-reporting issuers, we are unable to quantify the number of non-reporting issuers that might be affected by these decisions.

B. Analysis of the Amendments

The amendments will affect reporting issuers generally, and banks, bank holding companies and savings and loan holding companies specifically, as well as non-reporting issuers, employees and other investors. We analyze the costs and benefits associated with the amendments below.

1. Increased Regulatory Thresholds for Banks, Savings and Loan Holding Companies and Bank Holding Companies

As discussed above, the JOBS Act and the FAST Act amended Sections 12(g) and 15(d) of the Exchange Act to raise the thresholds at which banks, savings and loan holding companies and bank holding companies may terminate registration or suspend their obligations to file reports with the Commission from 300 to 1,200 holders of record.[120] However, without the amendments being adopted today, banks, savings and loan holding companies and bank holding companies that want to use the higher thresholds must wait 90 days after filing a certification with the Commission that the number of holders of record is less than 1,200 persons to terminate their Section 12(g) registration and cease filing reports required by Section 13(a) and must wait until the first day of the fiscal year to suspend any Section 15(d) reporting obligations. For other issuers, our existing rules afford procedural accommodations that allow them to suspend their reporting obligations immediately upon the filing of a certification on Form 15.

To make these procedural accommodations applicable to banks, savings and loan holding companies and bank holding companies, as proposed, the amendments revise Exchange Act Rules 12g–2, 12g–3, 12g–4 and 12h–3 to reflect the 1,200 holders of record threshold for banks, savings and loan holding companies and bank holding companies. This will permit banks, savings and loan holding companies and bank holding companies to rely on these rules to cease reporting during a fiscal year, rather than wait the 90 days or until the end of the reporting year prescribed under the Exchange Act. This will reduce issuer compliance and reporting costs during the fiscal year the issuer ceases reporting[121] and may lessen potential confusion that could arise from the differences in the thresholds contained in the statute and our existing rules. At the same time, extending these procedural accommodations could accelerate the loss of investor access to current information about the issuer. We note, however that this effect is likely mitigated by the non-SEC regulatory disclosure requirements that will continue to apply to regulated banks, savings and loan holding companies and bank holding companies after adoption of today's amendments.

We believe that the amendments adopted under this rule will not have a significant impact on competition. To the extent that savings pursuant to lower compliance and reporting costs could possibly be used to increase institutions' lending activities, the amendments may lead to higher levels of investment and capital formation in the economy.

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[117] The Commission staff derived this estimate of the number of banks and bank holding companies that have elected to terminate registration or suspend reporting by analyzing Form 15 filings on EDGAR.

[118] The Commission staff derived this estimate by analyzing annual filings submitted to the Commission as of December 31, 2015 for the most recently completed fiscal year.

[119] *Id.* We note, however, that 25 of these 28 savings and loan holding companies are listed on a national securities exchange and required to report under Section 12(b) of the Exchange Act. In order to cease reporting, these issuers would be required to delist from the exchange.

[120] For other issuers, the threshold in Section 12(g)(4) for termination of registration and in Section 15(d)(1) for suspension of reporting remains at 300 holders of record.

[121] *See* letter from ABA indicating that these costs could be especially onerous for financially distressed firms and from ICBA.

As stated above, we estimate that there are approximately 550 banks, savings and loan holding companies and bank holding companies that currently report with the Commission. Many of these reporting issuers have more than 1,200 holders of record and are not eligible to cease reporting under the new higher thresholds. However, approximately 192 of these reporting banks, savings and loan holding companies and bank holding companies have between 300 and 1,199 holders of record and may be eligible to cease reporting. Many of these banks and bank holding companies have likely been eligible to deregister or suspend reporting since the adoption of the JOBS Act, but have chosen to continue as reporting issuers. One explanation for why many of these issuers have chosen not to deregister is that most (143) are also listed on national securities exchanges and if they chose to deregister or suspend reporting under the Exchange Act, they would have to give up their national exchange listing.[122] While a higher percentage of savings and loan holding companies have become eligible to terminate their registration or suspend reporting under the FAST Act, approximately 50 of 64 reporting savings and loan holding companies are registered pursuant to Section 12(b). Based on staff research, most of the newly eligible savings and loan holding companies (approximately 25 of the 28) would have to delist from a national securities exchange to cease reporting under the Exchange Act.

We believe that the likelihood of large numbers of eligible banks, savings and loan holding companies and bank holding companies terminating registration or suspending reporting based on the new higher thresholds in future years is low. While a relatively larger number of banks and bank holding companies (69) relied on the new thresholds to exit Exchange Act reporting immediately after the adoption of the JOBS Act in 2012, the numbers of such issuers relying on the new thresholds to exit substantially decreased over the subsequent three years (18 in 2013, 7 in 2014 and 6 in 2015).[123] As banks and bank holding companies remain subject to other regulatory reporting requirements,[124] many have chosen to continue reporting, and bear ongoing reporting costs, even though they are eligible to cease reporting under Section 12(g) of the Exchange Act. We expect to see a similar trend with respect to the deregistrations of savings and loan holding companies.

In deciding whether to terminate registration or suspend their reporting obligations, we anticipate that banks, savings and loan holding companies and bank holding companies will weigh the benefits of being a public company against the burden of additional disclosure costs. Commonly cited benefits of being a public company include the ability to obtain a lower cost of capital for investment and growth, increased liquidity through a broader shareholder base, and greater ability to finance acquisitions and offer equity-based incentive contracts.[125] Commonly cited costs of being a public company include the need to comply with increased regulations and regulatory supervision, including requirements for independent audits,[126] disclosure of information to competitors, loss of control and ownership dilution.[127]

2. Use of the Term "Accredited Investor" in Exchange Act Section 12(g)

Section 501 of the JOBS Act raises the number of holders of record at which an issuer is required to register a class of equity securities under the Exchange Act from 500 persons to 2,000 persons or 500 persons who are not accredited investors. In order for an issuer to rely on the new, higher threshold established by the JOBS Act, the issuer must make accredited investor determinations if it has more than 500 holders of record.

We are amending Exchange Act Rule 12g–1 to clarify that the definition of "accredited investor" in Securities Act Rule 501(a) applies when making determinations under Exchange Act Section 12(g)(1) and that such determination must be made as of the last day of the fiscal year rather than at the time of sale of the securities. Under Rule 501(a), an accredited investor is any person who comes within one or more of the categories of investors specified therein, or who the issuer reasonably believes comes within any such category. Many issuers and investors are familiar with the Rule 501(a) definition as it is a central component for private offerings conducted under Securities Act Rule 506 of Regulation D.[128] Consequently, the amendment should facilitate compliance.[129] Developing an alternative definition for purposes of Section 12(g)(1) could impose costs on issuers and investors by requiring them to familiarize themselves with, and apply, a new and different standard.[130] Due to limitations in available data, we are unable to estimate how many issuers will be impacted by using the Rule 501(a) definition of "accredited investor."

Requiring issuers to make the accredited investor determination at the end of the fiscal year rather than at the time of sale of securities will ensure that the information is timely and consistent with issuers' facts and circumstances at the end of each year. Permitting an issuer to rely on an ongoing basis on information previously obtained relating to accredited investors status, such as allowing reliance on information obtained by the issuer at the time the securities were initially issued to the investor or at the time the securities were most recently issued to the investor, would likely be less costly than requiring the issuer to establish a reasonable belief that the investor is an accredited investor. This, however, could also lead to reliance on outdated information, potentially causing issuers with more than 500 non-accredited investors to fail to register, thereby leaving investors in those issuers with less information and protection under the federal securities laws.

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[122] Listing on a national securities exchange triggers current and periodic Exchange Act reporting requirements under Section 12(b).

[123] The Commission staff derived this estimate by analyzing Form 15 filings submitted to the Commission. These numbers indicate that approximately 4%, 1% and 1% of the reporting bank and bank holding companies deregistered during 2013, 2014 and 2015, respectively.

[124] The Board of Governors of the Federal Reserve System is responsible for the consolidated supervision of bank holding companies and savings and loan holding companies and requires those entities to provide data relating to capitalization, liquidity, and risk management as well as periodic financial reports in order for the Board of Governors to analyze the overall financial condition of those entities to ensure safe and sound operations.

[125] *See* J. Brau, *Why Do Firms Go Public?, Oxford Handbook of Entrepreneurial Finance* (2010) (providing a general discussion of the different rationales for firms to go public); U. Celikyurt, M. Sevilir, and A. Shivdasani, *Going Public to Acquire? The Acquisition Motive in IPOs,* J. FIN. ECON. (2010) (arguing that firms go public so as to facilitate acquisitions); M. Pagano, F. Panetta, and L. Zingales, *Why Do Companies Go Public? An Empirical Analysis,* J. FIN. (1998) (showing that initial public offerings are generally followed by lower cost of credit and increased turnover in control); T. Chemmanur and P. Fulghieri, *A Theory of the Going Public Decision,* REV. FIN.STUD. (1999) (arguing that going public broadens the ownership base of the firm); R. Rosen, S. Smart and C. Zutter, *Why Do Firms Go Public? Evidence From the Banking Industry,* Working Paper (2005) (finding that banks that go public are more likely to grow faster, earn higher profits, employ more leverage and become acquirers when compared to their non-reporting counterparts), available at *http://papers.ssrn.com/sol3/papers.cfm?abstract_id=686473.*

[126] *See* letter from IPA. IPA cited an estimate of ongoing reporting costs under the Exchange Act of $650,000 annually. This commenter additionally noted that becoming an Exchange Act reporting company may be contrary to an issuer's business plan and against investors' economic interests. *See also* letter from ABA positing that once the initial cost of implementing reporting procedures are undertaken, the ongoing costs of reporting are not a significant burden on capital formation and job creation.

[127] *See* J. Brau and S. Fawcett, *Initial Public Offerings: An Analysis of Theory and Practice,* J. FIN. (2006) (reporting based on a survey of CFOs that "desire to maintain decision-making control," "disclosing information to competitors," "SEC reporting requirements" and "to avoid ownership dilution" are among the top five reasons why firms choose to stay private); J. Farre-Mensa, *Why Are Most Firms Privately Held?,* Working paper, Harvard University (2011) (documenting that firms in industries with high disclosure costs (*i.e.,* where it is easier for competitors to appropriate a firm's intellectual property) tend to remain private), available at *http://www.cemfi.es/ftp/pdf/papers/wshop/Farre-Mensa_JobMarketPaper.pdf.*

[128] The Rule 501(a) definition is also used in connection with other unregistered offerings, for example for offerings conducted pursuant to amended Regulation A or the recently adopted Regulation Crowdfunding.

[129] *See* letter from ABA.

[130] *Id.*

Not providing specific guidance or rules on how to establish a reasonable belief of a security holder's status as an accredited investor for purposes of determining holders of record could result in some uncertainty and possibly higher costs for issuers. We believe, however, that the "reasonable belief" standard under Rule 501(a) provides issuers with appropriate flexibility to use the method that works best, given their individual circumstances, to determine the accredited investor status of their shareholders. We also believe that this standard may help to mitigate some of the concerns relating to higher costs under the adopted provision by allowing issuers to rely on previous/other determinations if they have a reasonable belief that the security holder continues to be or is an accredited investor. We also note that many issuers are familiar with and routinely use the "reasonable belief" standard without such guidance when making private offerings in reliance on Regulation D.

Some commenters recommended that the Commission address potential compliance issues related to the accredited investor threshold by providing a safe harbor for determining accredited investor status.[131] A safe harbor could increase efficiency by providing issuers with a prescribed process to determine and update the accredited investor status of their investors. For example, a safe harbor that permits an issuer to rely on an annual affirmation of accredited investor status by the investor, other information obtained by the issuer or on a combination of a certification and other information may be less costly than requiring an issuer to establish a reasonable basis for its determination through other means. Similarly, a safe harbor with specified time limits on the permitted use of the information[132] or conditioned upon the issuer not having information that the previously obtained information was incorrect, unreliable or had changed could address some of the concerns related to higher costs or outdated information. Another alternative would be a safe harbor that permits an issuer to rely on a third-party certification for determining the accredited investor status of investors.[133]

Despite the benefits described above, providing a specific method (or methods) under a safe harbor could become a *de facto* minimum standard which we believe would reduce the flexibility available to issuers for determining accredited investor status.[134] Moreover, at-least for some issuers, a prescribed method may be less accurate and more burdensome than alternate non-prescribed methods in establishing the accredited status of investors. For example, a safe harbor providing for annual certification could be costly and have adverse impacts on small issuers and their investors,[135] discouraging accredited investors from investing in their securities, and leading to lower levels of investment.[136]

3. Definition of "Held of Record" and Safe Harbor for Employee Compensation Plan Securities

Section 12(g)(5), as amended by Section 502 of the JOBS Act, excludes from the definition of "held of record" securities held by persons who received them pursuant to an employee compensation plan in transactions exempted from the registration requirements of Section 5 of the Securities Act for purposes of determining whether an issuer is required to register a class of security pursuant to Section 12(g)(1).[137] Section 503 of the JOBS Act directs the Commission to adopt a safe harbor that issuers can use when making their holder of record determinations.

We believe that, by making it easier for non-reporting companies that issue securities to their employees to remain below the registration and reporting thresholds in the Exchange Act, the statutory changes will benefit issuers by allowing them to better control how and when they become subject to reporting requirements, while continuing to use securities to compensate employees.[138] These changes could be particularly beneficial for smaller or cash-constrained issuers that could more easily issue securities to their employees as a form of compensation without being subject to Exchange Act reporting requirements and the associated compliance costs.

However, investors in these issuers, including employees, may be adversely affected by a delay in the potential registration of a class of securities and the associated reporting because they otherwise might benefit from the information provided through such reporting. As a result, the amendments to the definition of "held of record" and the non-exclusive safe harbor being adopted today could have an impact on the potential costs and benefits of Exchange Act registration for affected issuers and their investors by affecting areas such as the ease of relying upon the statutory exemption under Section 12(g), the number of non-reporting companies able to forestall registration, and the amount of information available to investors in those issuers' securities, with effects, for example, on price efficiency and liquidity. We further discuss the economic impact of specific aspects of these amendments below.

Instead of establishing a new definition for the term "employee compensation plan," we are amending the definition of "held of record" to permit an issuer to exclude securities held by persons who received them pursuant to an employee compensation plan in transactions exempted from, or not subject to, the registration requirements of Section 5 of the Securities Act and adopting a safe harbor providing that this condition will be satisfied if the securities were received pursuant to a compensatory benefit plan in transactions that meet the conditions of Rule 701(c). By not creating a new definition and relying on familiar concepts, the amendments should facilitate compliance and simplify recordkeeping by issuers.[139]

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[131] *See* letters from ABA, Foley and NYCBA. *See also* letters from ADISA, CFM, Cleary and IPA.

[132] *See* letter from Cleary suggesting a safe harbor permitting accredited investor status determinations made in offerings during the three months prior to fiscal year-end or on self-certifications by investors if the offering occurred more than three months but less than twelve months prior to fiscal year-end.

[133] *See* letter from IPA suggesting that relying upon third parties might allow issuers to reduce the cost of compliance for accredited investor determinations. We do not have adequate information about third-party certification providers and the characteristics of this industry to assess this alternative in terms of reliability and cost of the provided certification services. To the extent that reputational concerns would incentivize third-party certification providers to perform reliable and updated due diligence, third-party certification could potentially provide accurate information at a cost that economies of scale may lessen.

[134] *See* letter from ABA.

[135] *See* letter from IPA.

[136] *See* letter from CFM.

[137] Prior to the JOBS Act, employees who obtained securities under an issuer's employee compensation plan were not excluded from the shareholders of record calculation.

[138] *See* letter from ABA.

In a change from the proposal, we are revising the amendments to the definition of "held of record" to make clear that, in addition to securities issued to employees in transactions exempted from the registration requirements of Securities Act Section 5 (such as securities issued in a Rule 506 offering) or those issued to employees in transactions that did not involve a sale of securities within the meaning of Securities Act Section 2(a)(3), the amended definition also will permit issuers to exclude exempt securities issued to employees pursuant to Securities Act Section 3 (such as securities issued in a Regulation A or Rule 504 offering). The amendment will provide consistency in treatment of securities received pursuant to employee compensation plans in primary transactions that are exempt from Section 5 registration requirements or not subject to Section 5 registration requirements.[140] This could lower issuer costs and facilitate compliance. At the same time, such an expanded definition of "held of record" could reduce the number of holders of record of an issuer and potentially allow the issuers to delay or avoid Exchange Act reporting.

The amendments will permit issuers to exclude securities held by former employees who received the securities in a transaction exempt from, or not subject to, the registration requirements of Securities Act Section 5 in substitution or exchange for securities excludable under the proposed definition of held of record, as long as the former employees were eligible, at the time of issuance, to receive the original excludable securities. Relative to the proposal, the amended definition will also include such securities held by former employees who were employed by or providing services to a predecessor or an acquired company. By providing uniform treatment for all securities issued in exempt transactions, such provisions could lower issuer costs and facilitate compliance. Permitting exclusion of securities received by former employees and covered persons and securities exchanged or substituted for such original excludable securities also is likely to remove disincentives for issuers to engage in value-enhancing business combinations or other similar transactions,[141] which will benefit issuers and their investors. In this way, the amendments may also lead to a more efficient allocation of resources amongst firms that could improve growth prospects over the longer run.

As proposed, the amendments establish a non-exclusive safe harbor that issuers can rely on when determining whether holders of securities received pursuant to an employee compensation plan may be excluded. Consistent with the proposal, the safe harbor being adopted relies on the conditions in existing Rule 701(c). Relying on an existing standard that is already understood by market participants will make it easier for issuers to avail themselves of this safe harbor than if we proposed a new alternative standard. While generally broad in application, the conditions in Rule 701(c) impose certain limitations, such as requiring that securities be sold under a compensatory benefit plan, that the plan be written, that the plan be established by the issuer or certain specified related entities and that participation be limited to employees and certain other specified persons. Although we are unable to quantify the impact of adopting this safe harbor, as we cannot reliably predict the number of issuers that would rely on it, we can qualitatively assess its impact. A safe harbor that applies the familiar concepts of existing Rule 701(c) should create efficiencies in its application and avoid conflicts with existing rules, which could reduce costs, especially for smaller issuers.[142]

In a change from the proposal, the safe harbor also includes a reasonable belief standard. The inclusion of such a standard will obviate the need for issuers to re-establish that earlier issuances satisfied an appropriate exemption at the time of issuance. This should provide greater regulatory certainty, leading to lower compliance burdens for issuers.[143] Similarly, the interpretative guidance set forth in this release regarding transfers to family members of such exempt securities through the employee's death, disability or domestic relations order provides greater regulatory certainty with respect to specific circumstances that are unexpected or out of control of the issuer, which will benefit issuers intending to use equity compensation.[144]

Finally, as proposed, the amendments also provide that foreign private issuers will be able to rely on the adopted safe harbor when making their determination of the number of U.S. resident holders under Exchange Act Rule 12g3–2(a). While we are unable to quantify the number of foreign private issuers that will be impacted due to limitations in the available data, the amendments may allow some foreign private issuers to delay registering with and reporting to the Commission. The cost and benefit tradeoffs of Exchange Act registration for foreign private issuers will be analogous to the ones discussed above for domestic issuers. Additionally, the flexibility accorded by the amendments will benefit the U.S.-based employees of foreign private issuers by putting them on equal footing with employees in domestic private companies.[145]

V. Paperwork Reduction Act

Certain provisions of our disclosure rules and forms applicable to issuers contain "collection of information" requirements within the meaning of the Paperwork Reduction Act of 1995 ("PRA").[146] The hours and costs associated with preparing and filing forms and retaining records constitute reporting and cost burdens imposed by the collection of information requirements. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information requirement unless it displays a currently valid Office of Management and Budget ("OMB") control number. Compliance with the information collections is mandatory. Responses to the information collections are not kept confidential and there is no mandatory retention period for the collections of information.

The amendments adopted today do not alter the disclosure requirements set forth in our rules and forms; however, the JOBS Act and FAST Act amendments to Exchange Act Sections 12(g) and 15(d) and the amendments to our rules to reflect those statutory amendments are expected to insubstantially decrease the number of filings made pursuant to these rules and forms. Exchange Act Rules 12g–1, 12g–2, 12g–3, 12g–4 and 12h-3 set forth when an issuer's securities are required to be registered and the procedures for a registrant to terminate its registration or suspend its duty to file reports. The amendments provide thresholds that issuers may rely on when determining their registration and reporting obligations.[147] Exchange Act Section 12(g)(5) and the amendment to Exchange Act Rule 12g5–1 also exclude securities received pursuant to certain employee compensation plans from the determination of when an issuer is required to initially register with the Commission. These changes will reduce the number of registrants required to initially register a class of securities with the Commission as well as accelerate the ability of some registrants to cease filing after they have crossed below the statutory thresholds. For purposes of the PRA, as discussed below, we estimate that the amendments will not substantially reduce the number of filings received, nor will they affect the incremental burden or cost per filing.

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[139] *See* letter from ABA.

[140] *Id.*

[141] *Id.*

[142] *See* letter from ABA which states that Rule 701 is the primary exemption relied upon by smaller and other non-reporting issuers for such transactions.

[143] *Id.*

[144] *Id.*

[145] *Id.*

[146] 44 U.S.C. 3501 *et seq.*

The titles for the affected collections of information are:

(1) "Form 10" (OMB Control No. 3235–0064);[148]

(2) "Form 20–F" (OMB Control No. 3235–0288);[149]

(3) "Form 40–F" (OMB Control No. 3235–0381);[150]

(4) "Form 10–K" (OMB Control No. 3235–0063);[151]

(5) "Form 10–Q" (OMB Control No. 3235–0070);[152]

(6) "Form 8–K" (OMB Control No. 3235–0060);[153]

(7) "Schedule 14A" (OMB Control No. 3235–0059);[154]

(8) "Schedule 14C" (OMB Control No. 3235–0057);[155] and

(9) "Form 15" (OMB Control No. 3235–0167).

The forms were adopted under the Exchange Act and the Securities Act and set forth the disclosure requirements for periodic, current and other reports required to be filed by issuers registered with the Commission.

We estimate that there are approximately 579 Exchange Act registrants that are bank holding companies or savings and loan holding companies. We estimate that approximately 100 bank holding companies have filed Forms 15 to terminate or suspend their reporting obligations under the Exchange Act based on the statutory changes in the JOBS Act.[156] To put these numbers in context, the current PRA estimate for the number of annual reports on Form 10–K filed annually is 8,137. Moreover, for certain changes, such as the amendments to the definition of "held of record" in Rule 12g5–1, we do not have access to data to support a reliable estimate of the number of issuers that will not be required to file reports based on the JOBS Act amendments and our implementation of those amendments.

As explained in the Proposing Release, because the rule amendments are not expected to substantially impact the overall burden estimates associated with our rules and forms and in light of the limitations on available data, we have not submitted revised burden estimates for these collections of information to OMB for review in accordance with the PRA and its implementing regulations.[157] However, as we periodically update our PRA estimates in accordance with applicable regulations, we will make any necessary adjustments to reflect the actual number of filings received, including adjustments to reflect any reduction in filings arising from today's amendments.

VI. Final Regulatory Flexibility Act Analysis

This Final Regulatory Flexibility Act Analysis has been prepared in accordance with 5 U.S.C. 604. This analysis relates to the amendments to Securities Act Rule 405 and Exchange Act Rules 3b–4, 12g–1, 12g–2, 12g–3, 12g–4, 12g5–1, and 12h–3.

A. Need for, and Objectives of, the Action

The primary reason for, and objective of, the proposed amendments is to implement Title V and Title VI of the JOBS Act and Title LXXXV of the FAST Act. The JOBS Act directs the Commission to issue rules to implement the statutory changes and specifically charges the Commission with amending the definition of "held of record" and establishing a safe harbor for the determination relating to "employee compensation plan" securities. The amendments adopted today revise existing rules to reflect the new, higher Exchange Act registration, termination of registration and suspension of reporting thresholds for banks, savings and loan holding companies and bank holding companies, apply the definition of "accredited investor" in Securities Act Rule 501(a) in making determinations under Exchange Act Section 12(g)(1), revise the definition of "held of record" to exclude certain securities held by persons who received them pursuant to employee compensation plans, and establish a non-exclusive safe harbor for issuers to follow when determining whether those securities are "held of record." Additionally, revising the definition and providing a non-exclusive safe harbor to issuers relating to the determination of securities "held of record" will assist issuers in determining which holders of record they are required to count under the registration requirements of Exchange Act Section 12(g).

B. Significant Issues Raised by Public Comment

In the Proposing Release, we requested comment on all aspects of the Initial Regulatory Flexibility Act ("IRFA"), including the number of small entities that would be affected by the proposed amendments, the nature of the impact, how to quantify the number of small entities that would be affected and how to quantify the impact of the proposed amendments. We did not receive comments specifically addressing the IRFA. We did, however, receive comments from members of the public on matters that could potentially impact small entities. Several commenters recommended a safe harbor for the establishment of a reasonable belief of accredited investor status.[158] In contrast, one commenter opposed such a safe harbor out of concern that it would become a *de facto* minimum standard.[159] Commenters also sought additional guidance or revisions to the proposed amendment to Rule 12g5–1 and Securities Act Rule 701.[160]

C. Small Entities Subject to the Rule Amendments

Exchange Act Rule 0–10(a)[161] defines an entity, other than an investment company, to be a "small business" or "small organization" if it had total assets of $5 million or less on the last day of its most recent fiscal year. For purposes of the Regulatory Flexibility Act, an investment company is a small entity if it, together with other investment companies in the same group of related investment companies, has net assets of $50 million or less as of the end of its most recent fiscal year.[162] We estimate that there are approximately 841 issuers that file with the Commission, other than investment companies, that may be considered small entities.[163]

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[147] We also are amending Rule 12g–1 to reflect the new higher thresholds in Section 12(g)(1).

[148] 17 CFR 249.10.

[149] 17 CFR 249.220f.

[150] 17 CFR 249.240f.

[151] 17 CFR 249.310.

[152] 17 CFR 249.308a.

[153] 17 CFR 249.308.

[154] 17 CFR 240.14a–101.

[155] 17 CFR 240.14c–101.

[156] After the JOBS Act became effective, there was an increase in the number of termination and suspension of registrations by bank holding companies. We do not anticipate a similar rate of deregistration for bank holding companies after revising our rules to reflect the new, higher deregistration threshold. As the FAST Act was only recently enacted, we do not have data on the number of savings and loan holding companies seeking to deregister. However, we do not expect the rate of deregistration for savings and loan holding companies to be as high as for bank holding companies, as many of the newly eligible savings and loan holding companies (20 of 26) would have to give up an exchange listing in order to terminate registration and suspend reporting.

[157] 44 U.S.C. 3507(d); 5 CFR 1320.11.

[158] *See* letters from ADISA, CFM, Cleary, IPA. One commenter recommended a safe harbor for the determination specifically for private investment funds.

[159] *See* letter from ABA.

[160] *See* letters from ABA and ADISA.

[161] 17 CFR 240.0–10(a).

The rule amendments establishing the use of the Securities Act Rule 501(a) definition of "accredited investor" under Exchange Act Section 12(g)(1) and revising the definition of "held of record" to exclude certain securities and establish a non-exclusive safe harbor may affect small issuers relying on the revised rules and safe harbor to determine the number of holders of record. While an issuer is not required to register a class of equity securities pursuant to Section 12(g) of the Exchange Act until the issuer's total assets exceed $10 million, a small business or small organization may rely on the rules when determining to whom to issue securities and whether to compensate employees with securities. By providing guidance on the meaning of the term "accredited investor" in the Exchange Act context, the rule amendments may facilitate private offerings and the ability of an issuer to determine their registration and reporting obligations. By excluding certain employee compensation securities from the definition of "held of record," the rule amendments may facilitate the use of equity compensation by small issuers, thereby helping them to preserve cash and giving them greater ability to determine when the Exchange Act Section 12(g) registration obligation would be triggered.

We cannot reliably estimate the number of small entities affected by these rule amendments. By definition, such entities are not yet subject to Section 12(g) registration and reporting requirements, which are triggered by the issuer having total assets exceeding $10 million as of the last day of its fiscal year. We do not otherwise have information about the number of shareholders at small entities, including those who have received securities as a result of employee compensation plans.

D. Reporting, Recordkeeping and Other Compliance Requirements

The amendments' use of the Securities Act Rule 501(a) definition of "accredited investor" and the definition of "held of record" will assist an issuer in determining the number of holders of record. In order for an issuer to rely on the safe harbor, the securities must be issued in a transaction exempt from, or not subject to, the registration requirements of Securities Act Section 5 and satisfy the requirements of Securities Act Rule 701(c), which includes the requirement that the securities be offered or sold under a written compensatory benefit plan or written compensation contract. In addition, issuers seeking to rely upon the safe harbor may need to maintain records to help establish their compliance with the conditions of the safe harbor.

The rule amendments affecting banks, bank holding companies and savings and loan holding companies do not create any new reporting, recordkeeping or other compliance requirements for those entities. The rule amendments raise the thresholds relating to registration for those entities and therefore reduce their compliance burdens.

E. Agency Action To Minimize Effect on Small Entities

The Regulatory Flexibility Act directs us to consider significant alternatives that would accomplish the stated objective of our proposals, while minimizing any significant adverse impact on small entities. In connection with the rule amendments, we considered the following alternatives: (1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation or simplification of compliance and reporting requirements under the rule for small entities; (3) the use of performance rather than design standards; and (4) an exemption from coverage of the rules, or any part of the rules, for small entities.

We are applying the current definition of "accredited investor" in Securities Act Rule 501(a) in making determinations under Exchange Act Rule 12g–1(b)(1). Alternatively, we could have developed a new definition of "accredited investor" for purposes of Section 12(g)(1); however, given the prevalence of the use of Regulation D for exempt offerings, many issuers are familiar with and rely upon the definition in Rule 501(a). The increased registration threshold established by the JOBS Act is intended to permit issuers, including small entities, to defer Exchange Act registration until issuers have a larger shareholder base. Because proposed Rule 12g–1(b)(1) is intended to facilitate an issuer's ability to make the determination of when it is required to register, we believe use of the familiar performance standard in Rule 501(a) definition of "accredited investor" will further this regulatory objective for all issuers, including small entities.

We determined not to propose or adopt a safe harbor for the determination of accredited investor status. Requiring issuers to consider their particular facts and circumstances to establish a reasonable basis for their determination will provide issuers with flexibility in making the determination and diminish concerns that the information relied upon could be unreliable. Additionally, some standards that might be included in a safe harbor could, as one commenter noted, result in establishing a *de facto* minimum standard for the determination.[164] This could shift the standard from a performance standard to a design standard which would provide issuers with less flexibility when making the determination.

The revised definition of "held of record" and related safe harbor apply to all issuers, including small entities, that choose to exclude securities held by persons who received them pursuant to employee compensation plans in transactions exempt from, or not subject to, the registration requirements of Securities Act Section 5. The amendment and safe harbor help define the contours of an exemption from registration for issuers that might otherwise cross the Section 12(g) registration thresholds.

The amendments are intended to permit issuers, including small entities, to exclude certain securities from the "held of record" determination and to assist issuers in making that determination by clarifying and simplifying requirements for all entities. Establishing different compliance or reporting requirements relating to employee compensation plan securities or accredited investor determinations for small entities could complicate the rules and make them more difficult to apply as those issuers grow, cease to be small entities, and are required to determine whether they must register with the Commission. With respect to the use of performance standards rather than design standards, we note that the holder of record threshold is a statutorily created design standard, requiring issuers to register if their holders of record coupled with their total assets cross certain thresholds. As we are modifying the definition of "held of record" and clarifying the determination of "accredited investor" under this statutory design standard, we did not evaluate whether a performance standard would be more useful.

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[162] 17 CFR 270.0–10(a).

[163] The staff estimate is based on a review of Form 10–K, 20–F, 40–F filings (from EDGAR XBRL) with fiscal periods ending between January 31, 2015–January 31, 2016.

[164] *See* letter from ABA.

VII. Statutory Authority and Text of Rule Amendments

The amendments contained in this release are being adopted under the authority set forth in Section 19 of the Securities Act, as amended, Sections 3(b), 12(g), 12(h), 15(d) and 23(a) of the Exchange Act, as amended, and Section 503 and Section 602 of the JOBS Act.

List of Subjects in 17 CFR Parts 230 and 240

Reporting and recordkeeping requirements, Securities.

Text of the Amendments

For the reasons set out above, the Commission amends Title 17, chapter II of the Code of Federal Regulations as follows:

PART 230—GENERAL RULES AND REGULATIONS, SECURITIES ACT OF 1933

■ 1. The authority citation for part 230 continues to read, in part, as follows:

Authority: 15 U.S.C. 77b, 77b note, 77c, 77d, 77d note, 77f, 77g, 77h, 77j, 77r, 77s, 77z–3, 77sss, 78c, 78d, 78j, 78*l*, 78m, 78n, 78*o*, 78*o*–7 note, 78t, 78w, 78*ll*(d), 78mm, 80a–8, 80a–24, 80a–28, 80a–29, 80a–30, and 80a–37, and Pub. L. 112–106, sec. 201(a), sec. 401, 126 Stat. 313 (2012), unless otherwise noted.

* * * * *

■ 2. Amend § 230.405 by adding a Note to paragraph (1) of the definition of "Foreign private issuer" to read as follows:

§ 230.405 Definitions of terms.

* * * * *

Foreign private issuer. (1) * * *

Note to paragraph (1) of the definition of *Foreign private issuer:* To determine the percentage of outstanding voting securities held by U.S. residents:

A. Use the method of calculating record ownership in § 240.12g3–2(a) of this chapter, except that:

(1) The inquiry as to the amount of shares represented by accounts of customers resident in the United States may be limited to brokers, dealers, banks and other nominees located in:

(i) The United States,

(ii) The issuer's jurisdiction of incorporation, and

(iii) The jurisdiction that is the primary trading market for the issuer's voting securities, if different than the issuer's jurisdiction of incorporation; and

(2) Notwithstanding § 240.12g5–1(a)(8) of this chapter, the issuer shall not exclude securities held by persons who received the securities pursuant to an employee compensation plan.

B. If, after reasonable inquiry, the issuer is unable to obtain information about the amount of shares represented by accounts of customers resident in the United States, the issuer may assume, for purposes of this definition, that the customers are residents of the jurisdiction in which the nominee has its principal place of business.

C. Count shares of voting securities beneficially owned by residents of the United States as reported on reports of beneficial ownership provided to the issuer or filed publicly and based on information otherwise provided to the issuer.

* * * * *

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

■ 3. The general authority citation for part 240 is revised to read as follows:

Authority: 15 U.S.C. 77c, 77d, 77g, 77j, 77s, 77z–2, 77z–3, 77eee, 77ggg, 77nnn, 77sss, 77ttt, 78c, 78c–3, 78c–5, 78d, 78e, 78f, 78g, 78i, 78j, 78j–1, 78k, 78k–1, 78*l*, 78m, 78n, 78n–1, 78*o*, 78*o*–4, 78*o*–10, 78p, 78q, 78q–1, 78s, 78u–5, 78w, 78x, 78*ll*, 78mm, 80a–20, 80a–23, 80a–29, 80a-37, 80b–3, 80b–4, 80b–11, 7201 *et seq.*, and 8302; 7 U.S.C. 2(c)(2)(E); 12 U.S.C. 5221(e)(3); 18 U.S.C. 1350; Pub. L. 111–203, 939A, 124 Stat. 1376 (2010); and Pub. L. 112–106, sec. 503 and 602, 126 Stat. 326 (2012), unless otherwise noted.

* * * * *

■ 4. Amend § 240.3b–4 by redesignating the Instruction to paragraph (c)(1) as Note to paragraph (c)(1), and revising newly redesignated Note to paragraph (c)(1) to read as follows:

§ 240.3b–4 Definition of "foreign government," "foreign issuer" and "foreign private issuer".

* * * * *

(c) * * *

Note to paragraph (c)(1): To determine the percentage of outstanding voting securities held by U.S. residents:

A. Use the method of calculating record ownership in § 240.12g3–2(a), except that:

(1) Your inquiry as to the amount of shares represented by accounts of customers resident in the United States may be limited to brokers, dealers, banks and other nominees located in:

(i) The United States,

(ii) Your jurisdiction of incorporation, and

(iii) The jurisdiction that is the primary trading market for your voting securities, if different than your jurisdiction of incorporation; and

(2) Notwithstanding § 240.12g5–1(a)(8) of this chapter, you shall not exclude securities held by persons who received the securities pursuant to an employee compensation plan.

B. If, after reasonable inquiry, you are unable to obtain information about the amount of shares represented by accounts of customers resident in the United States, you may assume, for purposes of this definition, that the customers are residents of the jurisdiction in which the nominee has its principal place of business.

C. Count shares of voting securities beneficially owned by residents of the United States as reported on reports of beneficial ownership provided to you or filed publicly and based on information otherwise provided to you.

* * * * *

■ 5. Revise § 240.12g–1 to read as follows:

§ 240.12g–1 Registration of securities; exemption from section 12(g).

An issuer is not required to register a class of equity securities pursuant to section 12(g)(1) of the Act (15 U.S.C. 78*l*(g)(1)) if on the last day of its most recent fiscal year:

(a) The issuer had total assets not exceeding $10 million; or

(b) (1) The class of equity securities was held of record by fewer than 2,000 persons or 500 persons who are not accredited investors (as such term is defined in § 230.501(a) of this chapter, determined as of such day rather than at the time of the sale of the securities); or

(2) The class of equity securities was held of record by fewer than 2,000 persons in the case of a bank; a savings and loan holding company, as such term is defined in section 10 of the Home Owners' Loan Act (12 U.S.C. 1461); or a bank holding company, as such term is defined in section 2 of the Bank Holding Company Act of 1956 (12 U.S.C. 1841).

■ 6. Revise § 240.12g–2 to read as follows:

§ 240.12g–2 Securities deemed to be registered pursuant to section 12(g)(1) upon termination of exemption pursuant to section 12(g)(2)(A) or (B).

Any class of securities that would have been required to be registered pursuant to section 12(g)(1) of the Act (15 U.S.C. 78*l*(g)(1)) except for the fact that it was exempt from such registration by section 12(g)(2)(A) of the Act (15 U.S.C. 78*l*(g)(2)(A)) because it was listed and registered on a national securities exchange, or by section 12(g)(2)(B) of the Act (15 U.S.C. 78*l*(g)(2)(B)) because it was issued by an investment company registered pursuant to section 8 of the Investment Company Act of 1940 (15 U.S.C. 80a–8), shall upon the termination of the listing and registration of such class or the termination of the registration of such company and without the filing of an additional registration statement be deemed to be registered pursuant to section 12(g)(1) of the Act if at the time of such termination:

(a) The issuer of such class of securities has elected to be regulated as a business development company pursuant to sections 55 through 65 of the Investment Company Act of 1940 (15 U.S.C. 80a–54 through 64) and such election has not been withdrawn; or

(b) Securities of the class are not exempt from such registration pursuant to section 12 of the Act (15 U.S.C. 78*l*) or rules thereunder and all securities of such class are held of record by 300 or more persons, or 1,200 or more persons in the case of a bank; a savings and loan holding company, as such term is defined in section 10 of the Home Owners' Loan Act (12 U.S.C. 1461); or a bank holding company, as such term is defined in section 2 of the Bank Holding Company Act of 1956 (12 U.S.C. 1841).

■ 7. Amend § 240.12g–3 by revising paragraphs (a)(2), (b)(2), and (c)(2) to read as follows:

§ 240.12g–3 Registration of securities of successor issuers under section 12(b) or 12(g).

(a) * * *

(2) All securities of such class are held of record by fewer than 300 persons, or 1,200 persons in the case of a bank; a savings and loan holding company, as such term is defined in section 10 of the Home Owners' Loan Act (12 U.S.C. 1461); or a bank holding company, as such term is defined in section 2 of the Bank Holding Company Act of 1956 (12 U.S.C. 1841).

* * * * *

(b) * * *

(2) All securities of such class are held of record by fewer than 300 persons, or 1,200 persons in the case of a bank; a savings and loan holding company, as such term is defined in section 10 of the Home Owners' Loan Act (12 U.S.C. 1461); or a bank holding company, as such term is defined in section 2 of the Bank Holding Company Act of 1956 (12 U.S.C. 1841).

* * * * *

(c) * * *

(2) All securities of such class are held of record by fewer than 300 persons, or 1,200 persons in the case of a bank; a savings and loan holding company, as such term is defined in section 10 of the Home Owners' Loan Act (12 U.S.C. 1461); or a bank holding company, as such term is defined in section 2 of the Bank Holding Company Act of 1956 (12 U.S.C. 1841).

* * * * *

■ 8. Amend § 240.12g–4 by revising paragraph (a) to read as follows:

§ 240.12g–4 Certifications of termination of registration under section 12(g).

(a) Termination of registration of a class of securities under section 12(g) of the Act (15 U.S.C. 78*l*(g)) shall take effect 90 days, or such shorter period as the Commission may determine, after the issuer certifies to the Commission on Form 15 (§ 249.323 of this chapter) that the class of securities is held of record by:

(1) Fewer than 300 persons, or in the case of a bank; a savings and loan holding company, as such term is defined in section 10 of the Home Owners' Loan Act (12 U.S.C. 1461); or a bank holding company, as such term is defined in section 2 of the Bank Holding Company Act of 1956 (12 U.S.C. 1841), 1,200 persons; or

(2) Fewer than 500 persons, where the total assets of the issuer have not exceeded $10 million on the last day of each of the issuer's most recent three fiscal years.

* * * * *

■ 9. Amend § 240.12g5–1 by adding paragraph (a)(8) to read as follows:

§ 240.12g5–1 Definition of securities "held of record".

(a) * * *

(8)(i) For purposes of determining whether an issuer is required to register a class of equity securities with the Commission pursuant to section 12(g)(1) of the Act (15 U.S.C. 78*l*(g)(1)), an issuer may exclude securities:

(A) Held by persons who received the securities pursuant to an employee compensation plan in transactions exempt from, or not subject to, the registration requirements of section 5 of the Securities Act of 1933 (15 U.S.C. 77e); and

(B) Held by persons who received the securities in a transaction exempt from, or not subject to, the registration requirements of section 5 of the Securities Act (15 U.S.C. 77e) from the issuer, a predecessor of the issuer or an acquired company in substitution or exchange for excludable securities under paragraph (a)(8)(i)(A) of this section, as long as the persons were eligible to receive securities pursuant to § 230.701(c) of this chapter at the time the excludable securities were originally issued to them.

(ii) As a non-exclusive safe harbor under this paragraph (a)(8):

(A) An issuer may deem a person to have received the securities pursuant to an employee compensation plan if such plan and the person who received the securities pursuant to the plan met the plan and participant conditions of § 230.701(c) of this chapter; and

(B) An issuer may, solely for the purposes of Section 12(g) of the Act (15 U.S.C. 78*l*(g)(1)), deem the securities to have been issued in a transaction exempt from, or not subject to, the registration requirements of Section 5 of the Securities Act (15 U.S.C. 77e) if the issuer had a reasonable belief at the time of the issuance that the securities were issued in such a transaction.

* * * * *

■ 10. Amend § 240.12h–3 by revising paragraph (b)(1) to read as follows:

§ 240.12h–3 Suspension of duty to file reports under section 15(d).

* * * * *

(b) * * *

(1) Any class of securities, other than any class of asset-backed securities, held of record by:

(i) Fewer than 300 persons, or in the case of a bank; a savings and loan holding company, as such term is defined in section 10 of the Home Owners' Loan Act (12 U.S.C. 1461); or a bank holding company, as such term is defined in section 2 of the Bank Holding Company Act of 1956 (12 U.S.C. 1841), 1,200 persons; or

(ii) Fewer than 500 persons, where the total assets of the issuer have not exceeded $10 million on the last day of each of the issuer's three most recent fiscal years; and

* * * * *

By the Commission.

May 3, 2016.

Brent J. Fields,

Secretary.

[FR Doc. 2016–10746 Filed 5–9–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1150

[Docket No. FDA–2012–N–0920]

RIN 0910–AG81

Requirements for the Submission of Data Needed To Calculate User Fees for Domestic Manufacturers and Importers of Cigars and Pipe Tobacco

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is issuing a final rule that requires domestic manufacturers and importers of cigars and pipe tobacco to submit information needed to calculate the amount of user fees assessed under the Federal Food, Drug, and Cosmetic Act (the FD&C Act). FDA recently expanded its authority by issuing a final rule, "Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products" (Deeming rule), deeming all products that meet the statutory definition of "tobacco product," except accessories of the newly deemed tobacco products, to be subject to the FD&C Act. The Deeming rule, among other things, subjected domestic manufacturers and importers of cigars and pipe tobacco to the FD&C Act's user fee requirements. Consistent with the Deeming rule and the requirements of the FD&C Act, this final rule requires the submission of the information needed to calculate user fee assessments for each manufacturer and importer of cigars and pipe tobacco to FDA.

DATES: This rule is effective August 8, 2016. Domestic manufacturers and importers of cigars and pipe tobacco must begin submitting data required by § 1150.5 (21 CFR 1150.5) to FDA no later than the 20th day of August, 2016.

Because FDA can perform class allocations only on a full fiscal year basis, domestic manufacturers and importers of cigars and pipe tobacco will become subject to user fee assessments on October 1 of the first full fiscal year following the effective date of this rule.

FOR FURTHER INFORMATION CONTACT: Paul Hart, Food and Drug Administration, Center for Tobacco Products, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002; 1–877–287–1373, *CTPRegulations@fda.hhs.gov*.

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I. Background

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) was enacted on June 22, 2009 (Pub. L. 111–31), amending the FD&C Act and providing FDA with the authority to regulate tobacco products. Section 101(b) of the Tobacco Control Act amends the FD&C Act by adding chapter IX (sections 900 through 920 (21 U.S.C. 387 through 387u)). Chapter IX provides FDA with tools and funds to regulate tobacco products and imposes certain obligations on domestic tobacco product manufacturers and importers. Included among FDA's authorities are the authorities to assess and collect user fees.

In enacting the Tobacco Control Act, Congress found that tobacco use is the single most preventable cause of disease, disability, and death in the United States. Each year, over 400,000 people die prematurely from smoking or exposure to secondhand smoke. Approximately 8.6 million people in the United States live with a serious illness caused by smoking. A consensus exists within the scientific and medical communities that tobacco products are inherently dangerous and cause cancer, heart disease, and other serious adverse health effects (sections 2(2), (3), and (13) of the Tobacco Control Act).

The Tobacco Control Act grants FDA the authority to regulate tobacco products and to protect the public from the harmful effects of tobacco use. Section 901(b) of the FD&C Act automatically provides that chapter IX applies to cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. It also permits FDA to issue a regulation to deem other tobacco products subject to the FD&C Act, which FDA has done, by publishing elsewhere in this issue of the **Federal Register**, the Deeming rule to bring all products meeting the definition of tobacco product under its FD&C Act authority. More specifically, the Tobacco Control Act gives FDA the authority to, among other things:

- Restrict tobacco product retail sales to youth;
- require owners and operators of tobacco companies to register annually and be subject to biennial inspection by FDA (section 905 of the FD&C Act);
- require manufacturers and importers who wish to market a new tobacco product to obtain a marketing order from FDA prior to marketing that product (section 910 of the FD&C Act);
- require each manufacturer or importer to report all constituents, including smoke constituents as applicable, identified by FDA as harmful or potentially harmful to health in each tobacco product, and as applicable in the smoke of each tobacco product, by brand and by quantity in each brand and subbrand (section 904(a)(3) of the FD&C Act);
- establish tobacco product standards if FDA finds that it is appropriate for the protection of the public health (section 907(a)(3) of the FD&C Act);
- conduct compliance-check inspections of tobacco product retailers to determine a retailer's compliance with Federal laws and regulations;
- establish science and research programs to inform the development of tobacco product regulations and better understand the risks associated with tobacco use;
- educate the public about the harmful effects of tobacco use; and
- assess and collect user fees from each domestic manufacturer and importer of tobacco products subject to section 919 of the FD&C Act.

Section 919(c)(2) of the FD&C Act provides that tobacco product user fees are the sole source of funding for FDA's regulation of tobacco products. Therefore, FDA considers these fees to be critical to the Agency's ability to achieve its mission to protect and promote the public health. User fees provide FDA with a source of stable, consistent funding that has made possible our implementation of the Tobacco Control Act. The revenues from these fees fund the Agency's regulation of tobacco products and the tobacco industry, as described previously.

In the **Federal Register** of May 31, 2013 (78 FR 32581), FDA issued a notice of proposed rulemaking (User Fee proposed rule) to add 21 CFR part 1150 to require domestic tobacco product manufacturers and importers to submit information needed to calculate the amount of user fees assessed under the FD&C Act. FDA finalized portions of the User Fee proposed rule relating to tobacco products under FDA's jurisdiction at that time in the final rule

"Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products," which was published in the **Federal Register** of July 10, 2014 (79 FR 39302) (User Fee final rule). Elsewhere in this issue of the **Federal Register**, FDA is publishing the Deeming rule to deem all products meeting the statutory definition of "tobacco product," except accessories of the newly deemed tobacco products, to be subject to the FD&C Act. This rule is being issued in response to FDA's user fee authority over cigars and pipe tobacco, and finalizes portions of the User Fee proposed rule that relate to domestic manufacturers and importers of cigars and pipe tobacco, requiring them to submit information needed to calculate user fee assessments to FDA.

The final rule, issued under section 919(a) of the FD&C Act, requires FDA to assess user fees on, and collect such fees from, each manufacturer and importer of tobacco products subject to chapter IX of the FD&C Act. The total amount of user fees for each fiscal year is specified in section 919(b)(1) of the FD&C Act, and under section 919(a) we are to assess and collect a proportionate amount each quarter of the fiscal year. The FD&C Act provides for the total assessment to be allocated among the classes of tobacco products identified in the statute: Cigarettes, cigars, snuff, chewing tobacco, pipe tobacco, and roll-your-own tobacco. The class allocation is based on each tobacco product class' volume of tobacco products removed[1] into commerce that is not exempt from certain taxes. Within each class of tobacco products, an individual domestic manufacturer or importer is assessed a user fee based on its statutorily defined "percentage share" for that tobacco product class.

In specifying how to determine each of these two allocations—to a class of tobacco products and then to a domestic manufacturer or importer within a particular class of tobacco products—section 919 of the FD&C Act references the Fair and Equitable Tobacco Reform Act of 2004 (FETRA, Pub. L. 108–357 (7 U.S.C. 518 *et seq.*)). In determining the user fees to be allocated to each class of tobacco products, section 919(b)(2)(B)(ii) of the FD&C Act provides that the applicable percentage for each tobacco product class shall be the percentage determined under section 625(c) of FETRA for each such class of product for such fiscal year. The classes of tobacco products identified in section 919 of the FD&C Act are the same classes subject to assessments under FETRA. In determining the user fee to be paid by each company within a given class, except the cigar class, section 919(b)(4) of the FD&C Act directs that we use percentage share information determined for purposes of allocations under paragraphs (e) through (h) of section 625 of FETRA. With regards to cigars, section 919(b)(5) of the FD&C Act directs that the percentage share for each domestic manufacturer and importer be based on the excise taxes paid during the prior fiscal year, rather than the prior quarter.

FETRA provided for a Tobacco Transition Payment Program (TTPP) through which eligible former tobacco quota holders and tobacco producers received payments in 10 equal installments in each fiscal year 2005 through 2014. FETRA provided for the establishment of quarterly assessments on each domestic manufacturer and importer of tobacco products to fund the 10-year TTPP. The last assessment under FETRA was in September 2014, which encompassed the 39th and 40th quarterly TTPP assessments. The issuance of the 40th, or last, quarterly assessment, was on September 1, 2014, rather than on December 1, 2014, in accordance with statutory requirements specified in section 625(d)(3)(A) of FETRA. We are issuing this final rule consistent with section 919(b)(7) of the FD&C Act, which requires we ensure that we are able to make the determinations necessary for assessing tobacco product user fees.

II. Overview of the Final Rule

We are finalizing portions of the proposed rule with only minor changes. We amended § 1150.7(a)(1) and (2) to include language from the proposed rule specifying the calculations that FDA will perform to determine the yearly class allocation for cigars. Moreover, we added § 1150.9(a)(2) to codify the method by which FDA will calculate the percentage share for each domestic manufacturer and importer of cigars. In the proposed rule, we specifically discussed this proposed methodology, requested comment, and reserved § 1150.9(a)(2) for the purpose of including the calculations for manufacturers and importers in the cigar class if they became subject to chapter IX of the FD&C Act. After reviewing comments on the proposed rule, FDA is adding this methodology for cigars to § 1150.9(a)(2) without changes.

We added paragraph (c) to § 1150.5 to require that domestic manufacturers and importers of cigars report data for each prior month in the fiscal year in their first submission under this rule. Once deemed, cigars and pipe tobacco will be subject to user fees under section 919 of the FD&C Act. However, domestic manufacturers and importers of cigars and pipe tobacco will start being assessed fees only at the start of the fiscal year following the effective date of this rule because we can only perform class allocations on a full fiscal year basis. As we discussed in section I.B. of the User Fee proposed rule (78 FR 32583), section 919(b)(5) of the FD&C Act requires FDA to allocate user fees within the cigar class to cigar firms based on the amount of excise taxes those firms paid in the prior fiscal year. This addition to § 1150.5 will ensure that FDA has data for the prior fiscal year necessary to calculate, assess, and collect user fees for domestic manufacturers and importers of cigars in the first fiscal year in which they are assessed fees. We do not need data for the full prior fiscal year from domestic manufacturers and importers of other tobacco products subject to user fees, including pipe tobacco, because percentage share calculations for those classes only requires prior fiscal quarter data.

We added paragraph (d) to § 1150.5 to require that domestic manufacturers and importers of pipe tobacco begin their monthly reporting of data in August 2016. As noted previously, FDA makes percentage share calculations for tobacco products other than cigars using prior fiscal quarter data. Because FDA will begin making percentage share calculations for domestic manufacturers and importers of pipe tobacco beginning in the first fiscal quarter of 2017, FDA does not need pipe tobacco firms to submit data for months prior to the fourth fiscal quarter of 2016. Requiring domestic manufacturers and importers of pipe tobacco to make their first submission of prior month data by August 20, 2016, ensures FDA will have data for each month of the fourth fiscal quarter in 2016 and will be able to complete percentage share calculations for pipe tobacco firms for the first fiscal quarter of 2017.

Further, in light of the Deeming rule subjecting cigars and pipe tobacco to user fee requirements, we added 21 U.S.C. 387a and 21 CFR 1100.1 to the authority section. Finally, we amended § 1150.5(a) by removing the phrases "that are part of a class of tobacco products that is subject to regulation under chapter IX of the Federal Food, Drug, and Cosmetic Act" and "beginning October 2014." We made these changes because all classes of tobacco products that are included in the definition of "class of tobacco products" are subject to chapter IX of the FD&C Act and it is no longer necessary to make such a distinction, and because the October 2014 compliance date has passed.

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[1] Removal is defined at 26 U.S.C. 5702 as the removal of tobacco products or cigarette papers or tubes, or any processed tobacco, from the factory or from internal revenue bond under section 5704, as the Secretary of Treasury shall by regulation prescribe, or release from customs custody, and shall also include the smuggling or other unlawful importation of such articles into the United States.

III. Comments on the Proposed Rule

We received 12 comments on the proposed rule. We addressed a majority of the comments in the User Fee final rule. We declined to address comments relating to cigars, pipe tobacco, and other deemed products in that document because they were outside of FDA's jurisdiction at the time. Now that the Deeming rule has expanded FDA's authority to cover those products, we address the comments on assessing user fees on tobacco products that FDA deemed subject to chapter IX of the FD&C Act in this section.

Comments were received from tobacco product manufacturers, trade associations, and individuals. To make it easier to identify comments and our responses, the word "Comment," in parentheses, will appear before each comment, and the word "Response," in parentheses, will appear before each response. We have numbered the comments to make it easier to distinguish between comments; the numbers are for organizational purposes only and do not reflect the order in which we received the comments or any value associated with the comment. We have combined similar comments under one numbered comment.

(Comment 1) Multiple comments addressed FDA's authority to assess and collect user fees from domestic manufacturers and importers of products that have been deemed subject to FDA's jurisdiction, particularly e-cigarettes. Some comments stated that FDA must assess and collect fees because no "free riders" are allowed under section 919(a) of the FD&C Act. These comments relied on the language in section 919(a) of the FD&C Act that FDA shall assess user fees on, and collect such from, each manufacturer and importer of tobacco products subject to chapter IX. The comments asserted that, unless deemed products are subject to user fees, "some regulated manufacturers and importers would have to pay the cost of their regulation plus the cost of regulating the non-paying manufacturers and importers," which would provide the non-paying manufacturers and importers a significant competitive advantage in terms of reduced costs and prices for their products. Several of the comments claimed that failure to assess user fees on deemed products would violate the Fifth Amendment. Some comments also contend that exempting some products from user fees is unfair to existing classes, arbitrary and capricious, and would violate the Administrative Procedure Act.

In contrast, other comments stated that FDA does not have the authority to assess user fees for any class other than the six classes named in section 919(b)(2)(B) of the FD&C Act and in FETRA. These comments noted that section 919(a) provides that fees must be assessed and collected "in accordance with this section" and, therefore, FDA can assess fees only on those classes identified in section 919 and FETRA. One of these comments also noted that the reallocation provision in section 919(b)(2)(B)(iv) permits reallocation only to regulated classes of the six FETRA classes. Similarly, another comment stated that FDA cannot deem electronic cigarette manufacturers to meet the definition of domestic manufacturer because FDA "is bound under the FD&C Act to follow the allocation procedures established under FETRA."

(Response) Section 919(b)(2) of the FD&C Act lists six classes of tobacco products for the purpose of allocating among the classes—cigarettes, cigars, snuff, chewing tobacco, pipe tobacco, and roll-your-own tobacco. The comments raise the question of whether Congress intended FDA to assess fees for manufacturers and importers of tobacco products of only these six classes or intended that FDA create additional classes for other tobacco products and assess fees for them as well. In construing section 919 of the FD&C Act, FDA is confronted with two questions. First, has Congress directly spoken to the precise question presented? ("*Chevron* step one"); *Chevron, U.S.A., Inc.* v. *NRDC, Inc.*, 467 U.S. 837, 842 (1984). To find no ambiguity, Congress must have clearly manifested its intention with respect to the particular issue (*Young* v. *Community Nutrition Institute*, 476 U.S. 974, 980 (1986)). If Congress has spoken directly and plainly, the Agency must implement Congress' unambiguously expressed intent (*Chevron*, 467 U.S. at 842 to 843). If, however, section 919 is silent or ambiguous as to whether FDA must impose assessments on manufacturers and importers of only those classes of tobacco products listed in section 919(b)(2), FDA may determine whether section 919 should be interpreted to contain such a limitation, and FDA's interpretation must be upheld if it is reasonable ("*Chevron* step two"); *Chevron*, 467 U.S. at 842 to 843; *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132 (2000).

We have determined that, in enacting section 919 of the FD&C Act, Congress clearly manifested its intention that FDA only assess fees for manufacturers and importers of tobacco products in the six enumerated classes.

Section 919(a) of the FD&C Act states that FDA must assess fees "in accordance with this section," and section 919 provides a clear two-step process for assessing fees. The first step requires FDA to allocate fees to each class of tobacco products, which it does by multiplying the total amount of fees per year by the "applicable percentage" for each class. Section 919(b)(2)(A) of the FD&C Act. Section 919(b)(2)(B) of the FD&C Act sets forth how to calculate these applicable percentages, but only for the six classes enumerated in section 919(b)(2). The applicable percentage is the percentage determined under section 625(c) of Pub. L. 108–357, which is FETRA. Section 919(b)(2)(B)(ii) of the FD&C Act. Section 625(c) of FETRA provides initial percentages for each of the six classes, totaling 100 percent, and mandates that subsequent allocations be made only among these same classes. See sections 625(c)(1) and (2) of FETRA. Because the percentage of the total user fee assessment for each class under section 919 of the FD&C Act is the FETRA percentage, the sum of the percentages for all six classes will always total 100 percent. Since the six classes must comprise 100 percent of the allocation of the total user fee assessment under section 919(b)(2) of the FD&C Act, adding a class of tobacco product beyond the six would increase the total to over 100 percent. This is a result that Congress could not have intended, because it would require FDA to assess and collect user fees beyond the total amount permitted by section 919(b)(1) of the FD&C Act. Moreover, even assuming that under section 919 of the FD&C Act the applicable percentage for a class could be something other than the FETRA percentage, nothing in section 919 sets forth how FDA must, or even could, determine that percentage. Thus, this first step shows that section 919 is limited to the six classes enumerated in section 919(b)(2) of the FD&C Act.

The second step in the process for assessing fees is to determine the share of fees for each manufacturer and importer within each class of tobacco products. Except for the cigar class, this percentage shall be the percentage determined for the purposes of allocations under subsections (e) through (h) of section 625 of FETRA. Section 919(b)(4) and (5) of the FD&C Act. This directive makes clear Congress' intent that all classes except cigars (as discussed in the next paragraph) look to FETRA when calculating the percentage share of manufacturers and importers within a class. However, FETRA only yields, and by its text and structure can only yield, percentages for firms within the six listed classes. First, sections 625(e)(1) and (f) of FETRA provide allocations for each manufacturer and importer of tobacco products in each class "specified in subsection (c)(1)," which are the same six classes from section 919(b)(2) of the FD&C Act. Second, the FETRA allocations are based on each firm's share of the gross domestic volume for the class. Gross domestic volume is the volume of tobacco products "removed" and not exempt for Federal excise tax purposes. Section 625(a)(2) of FETRA. Thus, section 625(h) of FETRA sets forth the information required to be submitted to calculate the domestic volume of each manufacturer and importer, which relates to the removal of tobacco products for Federal excise tax purposes and the payment of such taxes. However, tobacco products outside the six classes listed in section 919 are not subject to Federal excise taxes, nor can such products be "removed" for Federal excise tax purposes. See 26 U.S.C. 52 and 26 U.S.C. 5702. Third, section 625(g) of FETRA provides measurement parameters to determine the volume of products removed, but they are explicitly limited to the six listed classes. The volume of domestic sales within a class are measured for the cigarette and cigar classes based on the number of cigarettes or cigars; for the remaining four classes specified in section 625(c)(1) of FETRA, they are measured based on the number of pounds. Because FETRA does not, and cannot, have allocations in the second step for products outside the six enumerated classes, it is clear that Congress intended only manufacturers and importers of tobacco products within those classes to be subject to user fees under section 919 of the FD&C Act.

This is reinforced by section 919(b)(5) of the FD&C Act, which sets forth a somewhat different process for calculating allocations among firms in the cigar class that is based on excise taxes paid during the prior fiscal year rather than the prior quarter. That provision says that the allocation among firms in the cigar class is "notwithstanding" section 919(b)(4) of the FD&C Act, showing that Congress intended the modified process for cigars to be an exception to the rule of using the FETRA framework to determine each firm's share of the class assessment. Because section 919 of the FD&C Act does not provide any other exceptions, the FETRA percentages must be used for the allocations within all other classes.

Section 919(b)(7)(A) of the FD&C Act likewise limits the assessment of fees under section 919 to the six listed classes. This provision requires FDA to obtain, from the appropriate Federal Agency, all necessary information regarding all tobacco product manufacturers and importers required to pay user fees in order to make percentage calculations for each class (*i.e.*, "applicable percentages of each class" under the statute, Section 919(b)(2)) and percentage share calculations within each class. As directed, FDA entered into a Memorandum of Understanding with the U.S. Department of Agriculture (USDA) to provide all the necessary information to FDA, and did so only for firms manufacturing or importing products in the six classes listed in section 919.[2] USDA could not provide "all necessary information" to FDA to make percentage share calculations for tobacco products in any other classes, nor could any other Federal Agency.

The reallocation provision in section 919 of the FD&C Act also shows that user fees cannot be imposed on products outside the six listed classes. This provision requires that the amount of user fees that would be otherwise be assessed to classes of tobacco products that are not subject to chapter IX of the FD&C Act must be reallocated to classes that are subject to chapter IX. Section 919(b)(2)(B)(iv) of the FD&C Act. This reallocation must be done in the same manner and based on the same relative percentages otherwise determined under section 919(b)(2)(B)(ii). By its terms, section 919(b)(2)(B)(ii) of the FD&C Act can provide the applicable percentages for only the six classes in section 919(b)(2)(B)(i) because those percentages are determined under section 625(c) of FETRA. Accordingly, FDA is unable to reallocate any user fees to a class outside of the six. Thus, the only way that FDA could reallocate fees to classes that are subject to chapter IX of the FD&C Act is for the tobacco product classes to be limited to those listed in section 919(b)(2)(B)(i) of the FD&C Act and in FETRA. Any other interpretation would render the reallocation provision's express linkage to FETRA superfluous and contravene the clear intent of Congress.

Generally, comments that asserted that FDA should assess fees on all deemed tobacco products, including those outside the six classes, point to section 919(a) of the FD&C Act, which says that FDA shall assess user fees on, and collect such from, each manufacturer and importer of tobacco products subject to chapter IX. They argue that if electronic nicotine delivery systems (ENDS) and other tobacco products are deemed to be subject to chapter IX, then each manufacturer and importer of such products is subject to these fees. These comments, however, fail to take into account section 919(a)'s mandate that the assessment shall be done "in accordance with this section." As described previously, when the assessments are made in accordance with section 919's two-step process, they yield assessments only for tobacco products in the six classes.

Moreover, it is clear that, for the purposes of section 919 of the FD&C Act, including 919(a), the term "each manufacturer and importer of tobacco products" is limited to the tobacco products in the six classes. By its terms, Congress intended section 919 to work in accordance with the FETRA framework. Section 625 of FETRA, like section 919 of the FD&C Act, applies to each "tobacco product manufacturer" and "tobacco product importer" and to each class of tobacco products. The terms manufacturer, importer, and tobacco product in section 919 of the FD&C Act and FETRA flow from the Internal Revenue Code (IRC). 26 U.S.C. 5702. Just as section 919 requires FDA to make the allocations—both for each class and within each class—based on FETRA, the FETRA allocations are based on removals for the purposes of Federal excise taxes. Thus, section 919 of the FD&C Act and FETRA, and their respective implementing regulations, use the same terms used in the IRC relating to Federal excise taxes. The classes of tobacco products are likewise consistent among the IRC, FETRA, and section 919 of the FD&C Act. The IRC defines six classes of tobacco products for Federal excise tax purposes.[3] The same six classes are enumerated in FETRA and section 919 of the FD&C Act for use in assessing the TTPP and tobacco user fees, respectively. Accordingly, in the IRC, FETRA, and section 919 of the FD&C Act, tobacco manufacturers are those who manufacture tobacco products in those six classes subject to Federal excise taxes. Any other approach to the term "each manufacturer and importer of tobacco products" in section 919 of the FD&C Act would lead to absurd results that Congress could not have intended. For example, section 900(20) of the FD&C Act defines "tobacco product manufacturer" as any person, including any repacker or relabeler, who manufactures, fabricates, assembles, processes, or labels a tobacco product. Relying on the section 900(20) definition would require FDA to assess user fees on each firm in the supply chain that, among other things, repacks, relabels, or distributes tobacco. However, doing so is impossible under the FETRA calculus mandated for the six classes under section 919 of the FD&C Act because FETRA calculates the relevant percentages based on the volume of product removed into domestic commerce (as defined by section 5702 of the IRC), and not tax exempt. Section 625(a)(2) and (3), (c)(2), (e) and (g) of FETRA. Some firms included in the section 900(20) of the FD&C Act definition of manufacturer, such as repackers and relabelers, do not "remove" products into domestic commerce as defined by the IRC because they are not removing products from a factory or bonded warehouse. Accordingly, these firms would not have a calculable volume of product removed into domestic commerce; as such, FDA could not calculate the user fees those firms would be assessed under section 919(b)(4) of the FD&C Act, nor could it determine how those firms affect class allocations under section 919(b)(2)(B) of the FD&C Act.

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[2] USDA's authority to collect assessments under FETRA has sunset. Section 919(b)(7)(B) of the FD&C Act requires FDA to ensure that it is able to determine the applicable percentages described in section 919(b)(2) and the percentage shares described in section 919(b)(4). Thus, FDA issued a rule in July 2014, as well as this rule to require the submission of the necessary information to determine these percentages, which enables FDA to assess and collect the tobacco product user fees.

[3] The IRC definition of tobacco product includes five classes, including 'smokeless tobacco,' which is further defined to comprise two classes of tobacco

In contrast, using the definitions for manufacturer and importer in the IRC, and as adopted in USDA's and FDA's implementing regulations, allows FDA to make the necessary user fee allocations. This approach limits the entities to be assessed fees to those that must obtain a permit from the Alcohol and Tobacco Tax and Trade Bureau (TTB) because they meet the definition of manufacturer of tobacco products or importer under the IRC and its implementing regulations (27 CFR 40.11 and 41.11). Only these entities are subject to Federal excise taxes under chapter 52 of the IRC and can "remove" tobacco products into domestic commerce. Thus, only these entities have a volume of domestic sales under FETRA and can be assessed user fees under section 919 of the FD&C Act.

Additionally, section 919 of the FD&C Act directly contradicts the section 900(20) definition in the manner it treats manufacturers and importers of tobacco products. Whereas the former treats manufacturers and importers as distinct entities for the purpose of assessments and collections, the section 900(20) definition includes importer as a subset of manufacturer, since the latter includes any person who imports a finished tobacco product for sale or distribution in the United States. Thus, Congress did not intend FDA to use the section 900(20) definition for the purposes of section 919.

Likewise, Congress could not have intended section 919 of the FD&C Act to incorporate the definition of "tobacco product" in section 201(rr) (21 U.S.C. 321(rr)) or the tobacco product definitions from section 900 of the FD&C Act. The former includes any "component, part, or accessory" of a tobacco product, which is significantly broader than the definitions for the different types of tobacco products in the IRC and FETRA. Similarly, the definition of "cigarette" in section 900(3) of the FD&C Act includes roll-your-own tobacco for cigarettes. If FDA calculated user fee assessments relying the definitions of "cigarette" and "roll-your-own" found in section 900(3) and 900(15) of the FD&C Act, respectively, manufacturers and importers of roll-your-own cigarettes would be required to pay fees both as part of the cigarette class and as part of the roll-your-own class. Such duplicative assessments would run contrary to section 919(b)(3)(B) of the FD&C Act, which expressly precludes manufacturers and importers from paying a user fee in excess of their percentage share. To prevent this, tobacco product classes must be distinct, and cannot overlap. Using the tobacco product definitions found in section 5702 of the IRC avoids double-billing firms because the classes are structured such that they are distinct and non-overlapping. Thus, for the term "each manufacturer and importer of tobacco products," Congress intended FDA to use the term in the IRC and FETRA.

While the definitions in sections 201(rr) and 900 of the FD&C Act say they apply for the purposes of the FD&C Act and chapter IX of the FD&C Act, respectively, this cannot be the case when doing so would run counter to the statutory purpose of a particular provision. Although there may be "a natural presumption that identical words used in different parts of the same act are intended to have the same meaning [citation omitted] . . . the presumption is not rigid. . . ." (*Atlantic Cleaners & Dryers, Inc.* v. *U.S.,* 286 U.S. 427, 433 (1932); (accord: *Yates* v. *U.S.,* 135 S. Ct. 1074, 1082 (2015)). Thus, the same words may be given different meanings, even in the same statute, if Congress intended different interpretations (at *Chevron* step one) or if such different interpretations are reasonable (at *Chevron* step two) (*Atlantic Cleaners & Dryers, Inc.,* supra). See also *Lawson* v. *Suwannee S.S. Co.,* 336 U.S. 198, 201 (1949); *Nw. Austin Mun. Util. Dist. No. One* v. *Holder,* 557 U.S. 193, 205 to 206 (2009). For the reasons given, it is clear that Congress intended the terms in section 919 to be consistent with the counterpart terms in FETRA and the IRC.

Nothing in the legislative history of section 919 of the FD&C Act undermines this view that user fees are limited to the six enumerated classes. To the contrary, this interpretation is reinforced by the legislative history of the Tobacco Control Act, which states that the method of assessing fees shall be the same as that currently used by United States Department of Agriculture for all tobacco manufacturers and importers to fund the 2004 legislation providing transitional payments to tobacco grower quota holders. H. Rpt. 111–58, p. 47. Because products other than those in the six listed classes are not "removed" and are not subject to a Federal excise tax, a user fee methodology for them could not be the same as that used by USDA under FETRA.

Having concluded that the statutory scheme precludes FDA from assessing user fees on classes of tobacco products beyond the six listed in section 919 of the FD&C Act, the Chevron analysis need not proceed further. However, in the alternative, even if section 919 of the FD&C Act is ambiguous as to whether classes beyond the six may be subject to user fee assessments, FDA would adopt the same interpretation of the statute in an exercise of its discretion. In conducting this *Chevron* step two analysis, the Agency has based its conclusion on the same considerations discussed previously as well as the considerations discussed later in this document (*Bell Atlantic Telephone Co.* v. *FCC,* 131 F.3d 1044, 1049 (D.C. Cir. 1997); *Chevron U.S.A., Inc.* v. *FERC,* 193 F. Supp. 2d 54, 68 (D.D.C. 2002)). FDA's interpretation of section 919 of the FD&C Act as assessing user fees only on the six classes of tobacco products listed

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products: Chewing tobacco and snuff. 21 U.S.C. 5702(c), (m).

in section 919(b)(2)(B)(ii) of the FD&C Act is reasonable. (*Chevron, USA, Inc.* v. *NRDC, Inc.*, supra at 843).

FDA's interpretation is consistent with the text and statutory structure of section 919. The statute requires FDA to use the FETRA percentages, and thus the FETRA formula, to determine the applicable percentages of the six classes listed in section 919(b)(2)(B)(i) of the FD&C Act, but it gives no indication of the manner under which FDA could or should determine user fee allocations for any additional classes. By using the FETRA framework, the applicable percentages for the six classes listed in section 919(b)(2)(B)(ii) are determined by a basic and predictable calculation. In addition, the user fee calculation is based on the share of gross domestic volume, which is inextricably linked to the volume of tobacco products removed that are subject to Federal excise taxes—information that was readily available to FDA at the time the Tobacco Control Act was enacted. For these six classes, Congress thus provided an easy-to-implement system that gives FDA relatively little discretion in determining the assessments.

As discussed previously, the class percentage for classes beyond the six cannot be determined pursuant to the FETRA framework since those classes do not have volumes as defined in section 625(a) of FETRA. Thus, in order to assess any user fees on any class of tobacco products beyond the six listed in section 919 of the FD&C Act, FDA would need to demarcate a new set of tobacco product classes among newly deemed tobacco products, and fashion an entirely novel framework for determining class percentage allocations and allocations within each class of tobacco product. It would have to do this against the backdrop of the range of tobacco products, including various types of ENDS (such as e-cigarettes, e-cigars, e-hookah, vape pens, personal vaporizers, and electronic pipes), as well as nicotine gels, nicotine toothpicks, etc.

Even if section 919 of the FD&C Act somehow allowed FDA to allocate percentages to and among additional classes, nothing in section 919 sets forth the methodology FDA must, or even could, use to calculate these percentages or how FDA would obtain the necessary information for doing so. Since 100 percent of the total amount of user fees to be assessed are allocated among the six classes listed in section 919(b)(2)(B)(ii) of the FD&C Act, FDA would need to devise a common metric for comparing each of these novel tobacco product classes to those six listed in order to adjust the relative class percentages (and find authority under section 919 to make such adjustments). FDA could not use the common metric adopted by USDA and, subsequently, by FDA in its 2014 final rule. This is based on the 2003 maximum Federal excise tax rates, which do not exist for tobacco products beyond the six classes. Further, because section 919(b)(2)(B)(ii) of the FD&C Act states that the applicable percentages for the six listed classes are the percentages from FETRA, for FDA to adjust those percentages based on a novel common metric external to FETRA would violate the statutory terms of that section.

Some commenters argued that FDA could and should abandon the tax-based methodology from FETRA altogether and create an entirely novel system unrelated to taxes or tax rates for determining the applicable percentages for both new and existing tobacco product classes. However, this suggestion also falters against the plain language of section 919(b)(2)(B)(ii) of the FD&C Act, which requires FDA to use the FETRA percentages for the six listed classes; deviating from FETRA's methodology for allocations would contradict the clear intent of Congress. Moreover, it is reasonable to conclude that Congress did not intend FDA to develop a new system that departs from the methodology mandated by FETRA. Any such system would necessarily be subjective, especially relative to the system Congress established for the enumerated six classes. As such, FDA's interpretation is a reasonable construction of the FD&C Act.

We disagree with commenters that a failure to assess fees on all deemed tobacco products is arbitrary and capricious. FDA is implementing the system established by Congress, which does not allow FDA to assess user fees for products outside the six classes. Even assuming section 919 of the FD&C Act is ambiguous regarding this point, for the reasons previously stated, FDA's interpretation here is reasonable. We also disagree with comments that argued that FDA's proposed scheme amounts to a tax because there is no tangible benefit to manufacturers and importers required to make user fee payments vis-à-vis those that are not, as required under the Independent Offices Appropriations Act (IOAA). Because Congress granted FDA independent statutory authority to assess user fees, the requirements of the IOAA do not apply. See *American Medical Ass'n* v. *Reno*, 857 F. Supp. 80, 84 (D.D.C. 1994); *National Cable Television Ass'n, Inc.* v. *United States*, 415 U.S. 336 (1974). Finally, we do not need to address commenters' Fifth Amendment arguments here because the FD&C Act itself differentiates between the six classes listed in section 919(b)(2)(B)(ii) and other tobacco product classes. As explained, FDA is merely following Congress' intent as expressed in section 919 of the FD&C Act.

(Comment 2) One comment stated that FDA should formulate a reasonable common metric to assess user fees on all regulated tobacco products, including those not subject to excise taxes. This comment said that a common metric was needed to compare new classes of tobacco products with existing classes and suggested that FDA "could base its calculations on total sales (in units) of each tobacco product, using traditional selling-sizes or weights of packages (*e.g.*, 20 cigarettes = 1 e-cigarette cartridge = 1 standard container of moist snuff = 4 large cigars) to derive the conversion factor necessary for market share calculations." Another comment stated that FDA should develop a method for calculating user fees for deemed products, not within the six classes, before any deeming regulation takes effect.

(Response) FDA disagrees with these comments. As discussed in the response to comment 1, section 919 of the FD&C Act prevents FDA from assessing and collecting user fees from manufacturers and importers of deemed products other than cigars and pipe tobacco. Creating a common metric among all product classes subject to FDA regulation would not change the requirements of section 919 of the FD&C Act that prevent FDA from assessing user fees for deemed products other than cigars and pipe tobacco.

(Comment 3) One comment stated that FDA should not adopt the USDA's retrospective calculation method for determining class percentage allocations at Step A because of concerns that a regulation deeming additional products subject to FDA regulation could dramatically alter class allocations from year to year, and that class allocation calculations using this method will not be an accurate reflection of each class' current percentage allocation. This comment stated that small businesses may no longer be able to sell deemed products withdrawn from the market due to premarket authorization requirements, but may still have to pay their share of their respective classes' user fees. Other companies that market grandfathered deemed products, the comment argued, would be forced to pay a disproportionate share based upon a class determination that was calculated before the deeming regulation. The comment requested that

FDA include safeguards against inequitable retrospective user fee requirements or allow for the continued marketing of deemed products while their corresponding premarket applications are pending review.

(Response) FDA disagrees with this comment. FDA is unable to alter the user fee calculations required by section 919 of the FD&C Act. In determining the user fees to be assessed on each class of tobacco products, section 919(b)(2)(B)(ii) of the FD&C Act provides that the applicable percentage for each tobacco product class shall be the percentage determined under section 625(c) of FETRA for each such class of product for such fiscal year. Relying on the initial allocation percentages in section 625(c) of FETRA, USDA calculated the yearly class allocations for each fiscal year based on data about removals covering the most recent full calendar year (see 70 FR 7007). As such, FDA's class allocations are calculated in the same manner. Section 919 also requires FDA to calculate assessments on each manufacturer and importer within a class on a quarterly basis using the prior quarter's tax removal data for products other than cigars and the prior fiscal year's tax removal data for cigars. While it is true that class allocations between product classes and percentage shares between companies within product classes can fluctuate throughout the year, FDA cannot alter the required method of user fee calculations.

(Comment 4) One comment argued that premium cigars should be exempt from FDA regulation generally and user fees specifically because FDA regulation would be disproportionately burdensome for the product segment, as exemplified by the new product (or premarket) requirements that would be triggered by the often minor ingredient variations intended to alter the taste and aroma of a premium cigar.

(Response) FDA disagrees with this comment. In the Deeming rule, FDA concluded that all cigars should be deemed subject to chapter IX of the FD&C Act and, in doing so, took into account the concerns about premarket authorization requirements raised in this comment. All cigars have been deemed subject to FDA's regulation and, as such, are subject to user fees under section 919 of the FD&C Act. Furthermore, FDA lacks the authority to exempt any portion of a class that has been deemed subject to chapter IX of the FD&C Act from user fee requirements.

(Comment 5) FDA received comments addressing the calculation of user fee assessments for domestic manufacturers and importers of cigars. One commenter asserted that using the amount of excise tax paid to determine percentage share within the cigar class would favor importers over domestic manufacturers because importers "can typically sell cigars to distributors at a lower price" because they benefit from lower wages, taxes, and regulatory costs. The commenter stated that actual units (sticks) would better reflect true market share and using excise taxes paid to calculate percentage share would increase incentives to move production and jobs off-shore.

Another comment suggested that FDA consider the differences in taxation of cigars compared with other taxable classes of tobacco products and assess the rule's "potentially inequitable impact on cigar manufacturers and importers." The comment asserted that the different excise tax rates applied within the cigar class would have the "unintended consequence" of causing manufacturers and importers of similar products to pay dramatically different amounts in user fees. The commenter further stated that large cigars have different first wholesale prices, and that some of these pricing differences are due to economies of scale or other efficiency factors. Companies with significant economies of scale would benefit by paying lower user fees due to their products being produced at lower cost, while small manufacturers and importers would be disadvantaged.

(Response) FDA disagrees with the suggestion that it can use something other than excise taxes to calculate the percentage share of manufacturers and importers in the cigar class. Section 919(b)(5) of the FD&C Act specifies that "if a user fee assessment is imposed on cigars, the percentage share of each manufacturer or importer of cigars shall be based on the excise taxes paid by such manufacturer or importer during the prior fiscal year." We acknowledge that this method of calculating cigar manufacturers' and importers' percentage share depends on the excise tax rate and would result in manufacturers and importers of small cigars paying a lower dollar amount of user fees per stick than manufacturers and importers of large cigars because large cigars are taxed at a higher rate than small cigars. However, we disagree that this would favor importers over domestic manufacturers and that it would encourage manufacturers to move abroad. Low volume, higher priced cigars are both more expensive and largely manufactured abroad. Importers of the higher priced cigars would pay more in user fees under the FD&C Act methodology than under a system in which volume was determined based on sticks.

In addition, we disagree that differences in user fee assessments across cigar types would be an unintended consequence of the FD&C Act methodology and that it would be inequitable. Cigars are a heterogeneous group of products, differing in such attributes as size and quality. The market for cigars is sufficiently competitive that price differences primarily reflect these product differences. It is not inequitable for products that differ greatly, as measured by market price, to pay different amounts of user fees. Moreover, the statute expressly states that each cigar manufacturer's or importer's percentage share must be calculated based on excise taxes paid. Congress thus clearly intended that user fees for cigars would vary depending on the excise taxes imposed on cigars, which in turn vary depending on the price and size of cigars.

IV. Legal Authority

Section 901 of the FD&C Act provides that chapter IX of the FD&C Act applies to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary of Health and Human Services by regulation deems to be subject to this chapter. In accordance with section 901, FDA is issuing the Deeming rule (published elsewhere in this issue of the **Federal Register**) to extend FDA's "tobacco product" authorities to products that meet the statutory definition of "tobacco product" in section 201(rr) of the FD&C Act, except the accessories of these tobacco products. Section 919(b)(7) of the FD&C Act requires that FDA ensure we are able to determine the applicable percentages described in section 919(b)(2) and the percentage shares described in section 919(b)(4). Section 909(a) of the FD&C Act authorizes FDA to issue regulations requiring tobacco product manufacturers or importers to make such reports and provide such information as may be reasonably required to assure that their tobacco products are not adulterated or misbranded and to otherwise protect public health. Under section 902(4), a tobacco product is deemed to be adulterated if the manufacturer or importer of the tobacco product fails to pay a user fee assessed to it under section 919 of the FD&C Act. In addition, section 701(a) of the FD&C Act (21 U.S.C. 371(a)) gives FDA general rulemaking authority to issue regulations for the efficient enforcement of the FD&C Act. Consistent with these authorities, FDA is issuing this rule, which is intended to ensure that we are able to make the determinations required by section 919 of the FD&C Act and assess and collect tobacco product user fees.

V. Environmental Impact

The Agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Economic Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601 to 612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). FDA has determined that this final rule is a significant regulatory action under Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The potential impact on small entities is uncertain, and FDA is unable to rule out the possibility that this final rule may have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $144 million, using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

Under our baseline, FDA would obtain the information necessary for collecting cigar and pipe tobacco user fees directly from other Federal Agencies that collect such information. Compared with this baseline, this final rule would impose both initial transition costs and monthly information submission costs on industry. There would also be an approximately offsetting reduction in government information collection costs. The net effect of this may be a small social cost or benefit. This final rule would also allow FDA to have full access to the data needed for calculating and billing user fees and would resolve impediments that may otherwise exist concerning FDA's ability to use the data for its intended purpose. This final rule can be expected to eliminate the potential need for additional regulatory mechanisms to collect information and allow user fee assessment to proceed more smoothly than it could otherwise.

Compared to the baseline, the estimated one-time private sector transition cost is $159.36 per manufacturer or importer, including small manufacturers and importers, and the annual compliance cost is $2,549.76. One option for regulatory relief would be to exempt firms from reporting in a particular month if they did not introduce any units of any tobacco products for which user fees are assessed into domestic commerce. Another option for regulatory relief would be to require submission of either the FDA form or copies of forms submitted to other Agencies. The full analysis of economic impacts is available as Ref. 1 in Docket No. FDA–2012–N–0920 and at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

VII. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown in the following paragraphs with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Tobacco Products, User Fees, Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Cigars and Pipe Tobacco.

Description: This final rule requires each domestic manufacturer and importer of cigars and pipe tobacco to submit to FDA information needed to calculate and assess user fees under the FD&C Act.

The USDA collected information to calculate percentage share for its purposes and provided FDA with the data FDA needs to determine user fee assessments under the FD&C Act. USDA ceased collecting this information at the end of fiscal year 2014. Consistent with the requirements of the FD&C Act, this rule continues the submission of this information, but to FDA rather than USDA, and thus ensures that FDA continues to have the information needed to calculate the amount of user fees assessed to each entity and collect those fees. Section 919 of the FD&C Act establishes the user fee allocation and collection process, which references the FETRA framework for determining tobacco product class allocations and individual domestic manufacturer or importer allocations. As was required by USDA under FETRA, the final rule requires domestic manufacturers and importers of tobacco products to submit to FDA each month a form with summary information and copies of the reports or forms that relate to the tobacco products removed into domestic commerce.

Description of Respondents: Domestic manufacturers and importers of newly deemed tobacco products.

The information collection provisions in this final rule have been submitted to OMB for review as required by section 3507(d) of the PRA. The requirements were approved and assigned OMB control number 0910–0749. This approval expires on July 31, 2017.

An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	No. of respondents	No. of responses per respondent	Total annual responses	Hours per response	Total hours
1150.5(a), (b)(1), (b)(2), and FDA Form 3852 (Ref. 2) General identifying information provided by manufacturers and importers of FDA regulated tobacco products and Identification and removal information (monthly)	135	12	1,620	3	4,860
1150.5(b)(3) Certified Copies (monthly)	135	12	1,620	1	1,620
1150.13 Submission of user fee information (Identifying information, fee amount, etc. (quarterly)	[2]68	4	272	1	272
1150.15(a) Submission of user fee dispute (annually)	1	1	1	10	10
1150.15(d) Submission of request for further review of dispute of user fee (annually)	1	1	1	10	10
Total					6,772

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

[2] This figure was rounded to the nearest tenth.

Table 1 describes the annual reporting burden of 6,772 hours as a result of the provisions set forth in this proposed rule. Our estimated number of 135 newly deemed respondents (335 total tobacco entities) is based on 2013 summary information obtained from the Alcohol and Tobacco Tax and Trade Bureau (TTB) regarding the number of permitted manufacturers and importers. As referenced previously, the PRA burden for currently regulated products was previously approved by OMB. The burden analysis for that collection assumed 200 respondents would submit user fees. Therefore given our updated estimate of 335 entities, the total number of new deemed tobacco entities is 135 (335 − 200 = 135). FDA estimates that there are 113 cigar manufacturers and 74 pipe tobacco manufacturers, as well as 216 importers of cigars and 43 importers of pipe tobacco. However, these estimates from TTB reflect that in 2013 there were 135 total permitted manufacturers and 200 permitted importers over all tobacco product types for which TTB collects excise taxes (including cigarettes, cigars, snuff, chewing tobacco, pipe tobacco, and roll-you-own tobacco, excluding electronic nicotine delivery systems). This total is less than the sum across all tobacco product types because some manufacturers and importers produce or import more than one type of tobacco product (we subsequently refer to these entities as polymanufacturers and polyimporters). As the number of cigar and pipe tobacco manufacturers cannot exceed the number of permitted entities, we use 335 as an upper bound estimate of the number of affected entities. The estimate of 135 respondents reflects both reports of no removal into domestic commerce and reports of removal of tobacco product into domestic commerce. The estimate of 68 respondents reflects an average number of domestic manufacturers and importers who may be subject to fees each fiscal quarter. FDA assumes half the number of respondents will submit quarterly payments to the Agency. Based on our experience with the assessment of user fees for other FDA-regulated products, we estimate that approximately one respondent might appeal an assessment, and one respondent will request for further review of their dispute.

VIII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that would have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

IX. References

The following references have been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov.* FDA has verified the Web site address, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. Regulatory Impact Analysis. Available at: *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

2. Form FDA 3852.

List of Subjects in 21 CFR Part 1150

Tobacco products, User fees.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 1150 is amended to read as follows:

PART 1150—USER FEES

■ 1. The authority citation for part 1150 is revised to read as follows:

Authority: 21 U.S.C. 371, 387a, 387b, 387i, 387s, 21 CFR 1100.1.

■ 2. In § 1150.3, revise the definition for "Units of product" to read as follows:

§ 1150.3 Definitions.

* * * * *

Units of product means:

(1) The number of sticks for cigarettes and cigars, or

(2) The weight (measured in pounds) for snuff, chewing tobacco, pipe tobacco, and roll-your-own tobacco.

* * * * *

§ 1150.5 [Amended]

■ 3. Amend § 1150.5 by:

■ a. Removing from the first sentence of paragraph (a) the phrases "that is subject to regulation under chapter IX of the Federal Food, Drug, and Cosmetic Act" and "beginning October 2014".

■ b. Adding paragraphs (c) and (d) to read as follows:

§ 1150.5 Required information.

* * * * *

(c) *First report for cigars.* Domestic manufacturers and importers of cigars must submit the information described in this section beginning no later than the 20th day of August, 2016. Domestic manufacturers and importers of cigars must submit the information described in this section for each of the prior months of fiscal year 2016 as their first monthly submission. The previous sentence only applies for the first report in fiscal year 2016.

(d) *First report for pipe tobacco.* Domestic manufacturers and importers of pipe tobacco must submit the information described in this section beginning no later than the 20th day of August, 2016.

* * * * *

■ 4. In § 1150.7, revise paragraph (a)(1) and add paragraph (a)(2) to read as follows:

§ 1150.7 Yearly class allocation.

* * * * *

(a) * * *

(1) Except for cigars, FDA will multiply the units of product removed and not tax exempt for the most recent full calendar year by the 2003 maximum Federal excise tax rate for that class (class dollar figure).

(2) For cigars, FDA will:

(i) Multiply the units of small cigars removed and not tax exempt for the most recent full calendar year by the 2003 maximum Federal excise tax rate for small cigars (small cigar subclass dollar figure).

(ii) Multiply the units of large cigars removed and not tax exempt for the most recent full calendar year by the 2003 maximum Federal excise tax rate for large cigars (large cigar subclass dollar figure).

(iii) Add the small cigar subclass dollar figure and the large cigar subclass dollar figure (cigar class dollar figure).

* * * * *

■ 5. In § 1150.9, revise paragraph (a)(1) and add paragraph (a)(2) to read as follows:

§ 1150.9 Domestic manufacturer or importer assessment.

* * * * *

(a) * * *

(1) For each class of tobacco products except cigars, FDA will calculate the percentage share for each domestic manufacturer and importer by dividing the Federal excise taxes that it paid for the class for the prior quarter by the total excise taxes that all domestic manufacturers and importers paid for the class for that same quarter.

(2) For the cigar class, FDA will calculate the percentage share for each domestic manufacturer and importer by dividing the Federal excise taxes that it paid for the class for the prior fiscal year by the total excise taxes that all domestic manufacturers and importers paid for the class for the prior fiscal year.

* * * * *

Dated: May 3, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–10688 Filed 5–5–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

Docket No. USCG–2015–0046

RIN 1625–AA09

Drawbridge Operation Regulation; Snake Creek; Islamorada, FL

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is modifying the operating schedule that governs the Snake Creek Bridge across Snake Creek, at Islamorada, FL. This final rule changes the drawbridge operating schedule for the Snake Creek Bridge by requiring it to open once an hour between 7 a.m. and 6 p.m. The Bridge Owner, Florida Department of Transportation and Local officials requested this action to assist in reducing vehicle traffic backups caused by bridge openings.

DATES: This rule is effective June 9, 2016.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type "USCG–2015–0046" in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rulemaking.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Coast Guard Sector Key West Waterways Management Division; telephone 305–292–8772, email *D07-DG-SECKW-WaterwaysManagement@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR	Code of Federal Regulations
DHS	Department of Homeland Security
E.O.	Executive order
FR	Federal Register
NPRM	Notice of proposed rulemaking
Pub. L.	Public Law
§	Section
U.S.C.	United States Code

II. Background Information and Regulatory History

The Snake Creek Bridge in Islamorada, Florida, has a vertical clearance of 27 feet in the closed position. The normal operating schedule as published in 33 CFR 117.331 is on demand except that from 8 a.m. to 4 p.m., the draw need open only on the hour and half-hour. This schedule has been in effect since 2001.

On March 27, 2015, we published a test deviation entitled Drawbridge Operation Regulations; Snake Creek; Islamorada, FL, in the **Federal Register** (80 FR 16280). We received 63 comments on the test deviation. No public meeting was requested, and none was held.

On September 18, 2015, we published a temporary interim rule and request for comments entitled Drawbridge Operation Regulations; Snake Creek; Islamorada, FL, in the **Federal Register** (80 FR 56381). We received 98 comments on the temporary interim rule. No public meeting was requested, and none was held.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority 33 U.S.C. 499.

Based on the following input, the Coast Guard initiated a test of a new schedule for the Snake Creek Bridge on May 27, 2015:

1. As reported by village and city councils, vehicle traffic caused by frequent openings of the Snake Creek Bridge negatively impacted Islamorada and surrounding communities. The temporary deviation successfully tested a new bridge operation schedule that reduced vehicle traffic caused by bridge openings.

2. On January 8–10, 2013, the Florida Department of Transportation conducted a traffic monitoring study 1400 feet south of the Snake Creek Bridge on US–1. The study found peak traffic volumes occurring around 08:45 a.m. and between 12:15 p.m. and 3:15 p.m. These peak traffic times were used to determine when the Snake Creek Bridge opening schedule could be limited to reduce traffic.

3. The Coast Guard's review found that the types of vessels navigating Snake Creek include sport fishing vessels and catamaran sailboats. Many of these vessels are able to safely transit under the Bridge in the closed position.

IV. Discussion of Comments, Changes and the Final Rule

During the comment periods for the temporary deviation and the temporary interim rule 161 comments were submitted to the docket. Sixty-three of those comment were received in response to the temporary deviation published on March 27, 2015 (80 FR 16280) and ninety-eight comments were received in response to the temporary interim rule published on September 18, 2015 (80 FR 56381).

One hundred and forty-four comments supported the amended operating schedule applied during the test deviation and the interim rule which allowed the Snake Creek Bridge to remain on a once an hour schedule between 8 a.m. and 6 p.m. seven days a week and on demand at all other times.

Six comments received opposed the amended operating schedule or suggested a different schedule that was more restrictive than necessary to accommodate vehicular traffic and did not accommodate the reasonable needs of maritime navigation.

Two commenters requested that the start time be moved to 7 a.m. to accommodate the school bus schedule. We agree that a schedule requiring the Snake Creek Bridge to open once an hour starting at 7 a.m. would assist with alleviating vehicular traffic and would not interfere with the reasonable needs of maritime traffic. Therefore, this final rule has been modified to begin the limited opening schedule at 7 a.m. instead of 8 a.m.

One comment suggested that these regulations were not needed after Labor Day. A review of the traffic logs shows that vehicle traffic does not diminish significantly after Labor Day.

One comment suggested the bridge remain on a twice an hour schedule except for weekends and Federal holidays. Based on a review of vehicle traffic patterns, vehicle traffic is heavy throughout the daylight hours and increases during weekends and Federal holidays. Reverting to a 30 minute schedule on weekends and Federal Holidays would cause excessive vehicle traffic which was the purpose of this change in operating schedule. Therefore, this rule does not make an exception for weekends and Federal Holidays.

Two comments suggested placing morning and afternoon curfew hours on this bridge. Placing morning and afternoon navigation closure periods on this bridge would have an overly restrictive impact on commercial waterway users and would not meet the reasonable needs of maritime traffic.

One comment suggested just three bridge openings a day. Allowing this bridge to open just three times during daylight hours would also have an overly restrictive impact on maritime traffic.

Four comments in the docket file were empty and provided no input.

These comments received during the interim rule comment period have been used to adjust this schedule.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders (E.O.s) related to rulemaking. Below we summarize our analyses based on a number of these statutes and E.O.s, and we discuss First Amendment rights of protesters.

A. Regulatory Planning and Review

E.O.s 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives, and, if regulation is necessary, to select regulatory approaches that maximize net benefits. E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has not been designated a "significant regulatory action," under E.O. 12866. Accordingly, it has not been reviewed by the Office of Management and Budget.

This regulatory action determination is made because vessels may navigate the Snake Creek Bridge during the scheduled opening times or use alternate passages including Channel Five above Long Key, Florida, which is approximately 5.7 nautical miles southwest of Snake Creek Bridge. Channel Five above Long Key, Florida is a fixed US–1 Bridge that has a vertical clearance of 65 feet. Also, vessels with adequate clearance may also pass under Snake Creek Bridge while it is in the closed position.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended, requires federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the bridge may be small entities, for the reasons stated above and in V.A., this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Government

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in E.O. 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a determination that this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This rule involves the operating regulations or procedures for drawbridges. Normally such actions are categorically excluded from further review, under figure 2–1, paragraph (32)(e), of the Instruction. This rule simply promulgates the operating regulations or procedures for drawbridges. This action is categorically excluded from further review, under figure 2–1, paragraph (32)(e), of the Instruction.

Under figure 2–1, paragraph (32)(e), of the Instruction, an environmental analysis checklist and a categorical exclusion determination are not required for this rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 117

Bridges.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

■ 1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 33 CFR 1.05–1; Department of Homeland Security Delegation No. 0170.1.

■ 2. Revise § 117.331 to read as follows:

§ 117.331 Snake Creek.

The draw of the Snake Creek Bridge, at Islamorada, Florida, will open on signal, except that from 7 a.m. to 6 p.m., the draw need open only on the hour.

Dated: May 4, 2016.

S. A. Buschman,

Rear Admiral, U.S. Coast Guard, Commander, Seventh Coast Guard District.

[FR Doc. 2016–10922 Filed 5–9–16; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[EPA–R08–OAR–2015–0205; FRL–9945–64–Region 8]

Designation of Areas for Air Quality Planning Purposes; Redesignation Request and Associated Maintenance Plan for Billings, MT 2010 SO_2 Nonattainment Area

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving the State of Montana's request to redesignate the Billings sulfur dioxide (SO_2) nonattainment area to attainment for the 2010 SO_2 primary national ambient air quality standards (NAAQS). The EPA has determined that the Billings SO_2 nonattainment area is attaining the 2010 SO_2 primary NAAQS. In addition, the EPA is approving Montana's maintenance plan which provides for continued attainment of the 2010 SO_2 primary NAAQS in the area. These actions are being taken under the Clean Air Act (CAA).

DATES: This final rule is effective on June 9, 2016.

ADDRESSES: EPA has established a docket for this action under Docket Identification Number EPA–R08–OAR–2015–0205. All documents in the docket are listed on the *http://www.regulations.gov* index. Although listed in the index, some information may not be publicly available, *e.g.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically through *http://www.regulations.gov* or in hard copy at the Air Program, Environmental Protection Agency (EPA), Region 8, 1595 Wynkoop Street, Denver, Colorado, 80202–1129. EPA requests that you contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section to view the hard copy of the docket. You may view the hard copy of the docket Monday through Friday, 8:00 a.m. to 4:00 p.m., excluding federal holidays.

FOR FURTHER INFORMATION CONTACT: Adam Clark, Air Program, U.S. Environmental Protection Agency, Region 8, Mailcode 8P–AR, 1595 Wynkoop, Denver, Colorado 80202–1129, (303) 312–7104, *clark.adam@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The EPA designated a portion of Billings, Montana, as nonattainment for the 2010 SO_2 NAAQS on August 5, 2013, (effective October 4, 2013) using 2009–2011 ambient air quality data, leaving the remaining portion of Billings and Yellowstone County undesignated and subject to future analysis and designation. *See* 78 FR 47191 (August 5, 2013).

On January 16, 2015, the State submitted a request for the EPA to determine that the Billings SO_2 nonattainment area has attained the 2010 SO_2 NAAQS per the EPA's "clean data policy." On December 14, 2015, the State submitted to the EPA a request for redesignation of the Billings 2010 SO_2 nonattainment area to attainment and a SIP revision containing a maintenance plan for the area.

On March 7, 2016, the EPA published a notice of proposed rulemaking (NPR) which proposed to approve the State's requests. *See* 81 FR 11733. Specifically, the EPA proposed to take the following four separate but related actions: (1) Determine that the Billings SO_2 nonattainment area is attaining the 2010 1-hour SO_2 NAAQS; (2) approve Montana's plan for maintaining the 2010 1-hour SO_2 NAAQS (maintenance plan); (3) redesignate the Billings SO_2 nonattainment area to attainment for the 2010 1-hour SO_2 NAAQS; and (4) determine that the Billings SO_2 nonattainment area has clean monitoring data. The details of Montana's submittal and the rationale for EPA's proposed actions are explained in the NPR and will not be restated here. The EPA received two public comments on the NPR, both of which supported the proposed redesignation. We acknowledge these supportive comments.

II. Final Action

The EPA is taking final actions on the redesignation request and maintenance plan submitted by the State of Montana on December 14, 2015 for the Billings 2010 SO_2 nonattainment area. The EPA is approving Montana's redesignation request because we have determined that the request meets the redesignation criteria set forth in section 107(d)(3)(E) of the CAA for this standard. The EPA finds that the monitoring data demonstrate that the area has attained the 2010 SO_2 NAAQS, and continues to attain the NAAQS as a result of the permanent and enforceable shutdown of the PPL Corette facility, whose emissions in 2009–2011 had been responsible for the area not previously meeting the NAAQS. The EPA is also approving the associated maintenance plan for the Billings 2010 SO_2 nonattainment area as a revision to the Montana SIP for the 2010 SO_2 NAAQS because it meets the requirements of section 175A of the CAA. Approval of this redesignation request will change the official designation of the Billings 2010 SO_2 nonattainment area to attainment for the 2010 SO_2 NAAQS.

III. Statutory and Executive Order Reviews

A. General Requirements

Under the CAA, redesignation of an area to attainment and the accompanying approval of a maintenance plan under section 107(d)(3)(E) are actions that affect the status of a geographical area and do not impose any additional regulatory requirements on sources beyond those imposed by state law. A redesignation to attainment does not in and of itself create any new requirements, but rather results in the applicability of requirements contained in the CAA for areas that have been redesignated to attainment. Moreover, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. *See* 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, these actions merely approve state law as meeting federal requirements and do not impose additional requirements beyond those imposed by state law. For this reason, these actions:

- Are not significant regulatory actions subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Do not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Are certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Do not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Do not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Are not economically significant regulatory actions based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Are not significant regulatory actions subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Are not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Do not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP does not apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the final rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

B. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

C. Petitions for Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by July 11, 2016. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. *See* section 307(b)(2).

List of Subjects

40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements, Sulfur dioxide.

40 CFR Part 81

Environmental protection, Air pollution control, Sulfur dioxide.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: April 18, 2016.

Shaun L. McGrath,

Regional Administrator, Region 8.

40 CFR parts 52 and 81 are amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart BB—Montana

■ 2. Section 52.1370, paragraph (e), under "(9) Yellowstone County" is amended by adding the entry "Billings 2010 SO_2 Maintenance Plan" at the end of the table to read as follows:

§ 52.1370 Identification of plan.

* * * * *

(e) * * *

Title/subject	State effective date	Notice of final rule date	NFR citation
* * * *	*	*	*
(9) Yellowstone County			
* * * *	*	*	*
Billings 2010 SO_2 Maintenance Plan	12/14/2015	5/10/2016	[Insert **Federal Register** citation].

■ 3. Section 52.1398 is added to read as follows:

§ 52.1398 Control strategy: Sulfur dioxide.

(a) *Redesignation to attainment.* The EPA has determined that the Billings 2010 sulfur dioxide (SO_2) nonattainment area has met the criteria under CAA section 107(d)(3)(E) for redesignation from nonattainment to attainment for the 2010 1-hour SO_2 NAAQS. The EPA is therefore redesignating the Billings 2010 SO_2 nonattainment area to attainment.

(b) The EPA is approving the maintenance plan for the Billings nonattainment area for the 2010 SO_2 NAAQS submitted by the State of Montana on December 14, 2015.

PART 81—DESIGNATION OF AREAS FOR AIR QUALITY PLANNING PURPOSES

■ 4. The authority citation for part 81 continues to read as follows:

Authority: 42 U.S.C. 7401, *et seq.*

Subpart C—Section 107 Attainment Status Designations

■ 5. Section 81.327, table "Montana—2010 Sulfur Dioxide NAAQS (Primary)" is amended by revising the entry for "Yellowstone County (part)" to read as follows:

§ 81.327 Montana.

* * * * *

Designated area	Designation Date	Designation Type
* * * * *	*	*
Yellowstone County (part) The area originates at the point defined as the southwest corner of Section 11, Township 1S, Range 26E. From that point the boundary proceeds north along the western section line of Section 11 to the point of intersection with the midline of Interstate Highway 90. From that point the boundary follows the midline of Interstate Highway 90, across the Yellowstone River, to the point where the highway midline intersects the northern boundary of Section 35, Township 1N, Range 26E. From that point the boundary proceeds east along the northern section line of Sections 35 and 36 to the point where Old US 87/Hardin Road leaves the section line and turns southeast. The boundary follows the midline of Old US 87/Hardin Road southeast to the point where the road intersects the western boundary of the SE 1/4 of the SE 1/4 of Section 31, Township 1N, Range 27E. From that point the boundary proceeds south along the 1/4 section line to the southern boundary of Township 1N, then east to the northeast corner of Section 5, Township 1S, Range 27E. The boundary then proceeds south along the eastern section line of sections 5 and 8 to the southeast corner of Section 8, Township 1S, Range 27E, where it turns west and follows the south section line of Sections 8 and 7, Township 1S, Range 27E; and Sections 12 and 11, Township 1S, Range 26E, back to the point of origin.	5/10/2016	Attainment.

* * * * *

[FR Doc. 2016–10451 Filed 5–9–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 258

[EPA–HQ–RCRA–2015–0126; FRL–9943–87–OLEM]

RIN 2050–AG75

Revision to the Research, Development and Demonstration Permits Rule for Municipal Solid Waste Landfills

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is publishing a final rule to revise the maximum permit term for Municipal Solid Waste Landfill (MSWLF) units operating under Research, Development and Demonstration (RD&D) permits. The RD&D permit program, which began in 2004, allows landfill facilities to utilize innovative methods that vary from the run-on control systems, liquids restrictions, and final cover criteria prescribed in 40 CFR part 258 if these systems are determined by the Director of an approved State to be at least as protective as those criteria. The current rule limits permits for these units to three years, and they are renewable three times for a total permit term of 12 years. This revision allows the Director of an approved State to increase the

number of permit renewals to six, for a total permit term of up to 21 years.

DATES: This final rule is effective on November 10, 2016.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–RCRA–2015–0126. All documents in the docket are listed on the *http://www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, *e.g.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Craig Dufficy, Materials Recovery and Waste Management Division of the Office of Land and Emergency Management (mail code 5304P), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460; telephone: 703–308–9037; email: *Dufficy.craig@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

Entities potentially affected by this rule are public or private owners or operators of MSWLFs. These entities include:

Category	Example of affected entities
State Governments	Regulatory agencies and agencies operating landfills.
Industry	Owners or operators of municipal solid waste landfills.
Municipalities, including Tribal Governments	Owners or operators of municipal solid waste landfills.

The affected entities may also fall under the North American Industry Classification System (NAICS) code 924110, Sanitation engineering agencies, government; or 562212, Solid Waste Landfill. This list of sectors is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that the EPA believes could potentially be regulated by this action. Other types of entities not listed in the table could also be regulated. To determine whether your entity is regulated by this action, you should carefully examine the applicability criteria found in 40 CFR part 258 and the Research, Development and Demonstration Permits for Municipal Solid Waste Landfills final rule, referred to as the "2004 RD&D rule" (69 FR 13242, March 22, 2004). If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

B. What action is the agency taking?

The EPA is revising the maximum permit term for MSWLF units operating under RD&D permits. The rule allows the Director of an approved State to issue up to six, 3-year permit renewals, for a total permit term of 21 years. The RD&D rule previously limited the total permit term to 12 years.

The primary basis for this extension of the permit period to up to 21 years is to provide the EPA more time to characterize the performance of RD&D projects without making the permit period so long as to be open-ended. The EPA believes that the period of 21 years strikes an appropriate balance between providing more time for projects to continue operations as research facilities, while providing enough time for the EPA to consider making additional changes to the part 258 MSWLF regulations.

C. What is the agency's authority for taking this action?

The authority for this rulemaking is sections 1008, 2002(a), 4004, 4005(c), 4010 and 8001(a) of the Resource Conservation and Recovery Act of 1976 (RCRA), as amended, 42 U.S.C. 6907, 6912(a), 6944, 6945(c), 6949a, 6981(a).

D. What are the anticipated effects and benefits of this action?

The anticipated effect of this action is to provide the Director of an approved State the ability to issue renewals to existing RD&D permits, as well as new RD&D permits, for up to 21 years instead of 12 years. During this time, the EPA will continue to evaluate data from these facilities. There are approximately 30 facilities currently operating with RD&D permits. It is also relevant to one facility operating on tribal lands under a site-specific action. Additional facilities may also seek an RD&D permit in the future. The EPA has no information with which to estimate whether any new facilities will seek RD&D permits. Owners/operators operating under existing RD&D permits are not expected to incur any new costs as a result of this final rule. The annual costs for ongoing recordkeeping and annual reporting requirements are estimated at $2,410 per facility.

It is important to note that applying for a RD&D permit remains voluntary. This action does not impose any new regulatory burden. This action allows the Director of an approved State to increase the number of extensions of the permit period for existing facilities, or offer more extensions of the permit term for new facilities, for those owners and operators who choose to participate in this research program. Increasing the possible number of extensions of the RD&D permit term may benefit current owners and operators of RD&D units by providing additional time to recover their costs, if the Director of an approved State chooses to extend existing permits. For example, data from one RD&D permitted facility show a projected increase of 3% in the rate of return for 20 years compared to 12 years.[1]

Increasing the possible number of extensions of RD&D permit terms is also expected to provide more time for the EPA to collect additional data on the potential benefits of the approaches being taken under these RD&D permits. These potential benefits include: Decreased costs for leachate treatment due to leachate recirculation in bioreactors; increased revenue from the sale of landfill gas for use as a renewable source of fuel; decreased risk due to a reduction in the transportation of leachate for treatment; accelerated production and capture of landfill gas for use as a renewable fuel; and accelerated stabilization and corresponding decreased post-closure care activities, for facilities as a result of the accelerated decomposition of waste.

II. Background

Under Subchapter IV of RCRA, 42 U.S.C. 6941–6949a, the EPA has promulgated minimum national standards for MSWLFs at 40 CFR part 258 (56 FR 50978, October 9, 1991). As specified in 42 U.S.C. 6981(a), RCRA also directs EPA to encourage research and development for, among other things, the development and application of new and improved methods of collecting and disposing of solid waste.

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[1] See docket item EPA–HQ–RCRA–2015–0126–0012, Smiths Creek Bioreactor Report.

The initial 1991 MSWLF regulations addressed seven basic areas: Location restrictions; operation; design; groundwater monitoring; corrective action; closure and post-closure care; and financial assurance. These MSWLF landfill regulations focused on dry-tomb landfills to minimize the possibility of groundwater contamination from the production and subsequent leakage of leachate. After the promulgation of those standards, the EPA became aware that landfill technology had advanced sufficiently that some alternative designs and operations could benefit from further study through research and demonstration projects. For example, some of these methods, particularly the addition of liquids and leachate recirculation, could accelerate biodegradation and provide additional potential benefits. These include:

—Acceleration of landfill gas generation which can be collected as a source of renewable fuel;

—minimization of leachate treatment requirements during the operational life of the landfill;

—more rapid reduction in concentration of leachate constituents of concern, thereby limiting the corresponding post-closure activities for leachate control; and

—an increase in the rate of landfill settlement resulting in the more efficient use of permitted landfill capacity.

As a means to advance innovation in landfill design, in 2000 the EPA selected four landfills to participate in its Project XL program,[2] all of which involved some use of bioreactor technology or leachate recirculation. The landfills are located in Buncombe County, North Carolina; Yolo County, California; King George County, Virginia; and the Maplewood facility in Amelia Country, Virginia.

In addition to Project XL, in 2001 the EPA began using Cooperative Research and Development Agreements (CRADAs) to promote collaborative research between federal and non-federal scientists as an additional means to explore the addition of liquids to landfills to promote faster biodegradation and stabilization. Bioreactor landfill sites operating with CRADAs include the Outer Loop landfill in Louisville, Kentucky; and the Polk County landfill in Florida.

Subsequently, in 2004, the EPA amended the part 258 MSWLF regulations to create a broader RD&D research program. The 2004 RD&D action (69 FR 13242, March 22, 2004), which added § 258.4, enabled the Director of an approved State to allow RD&D projects with variances to specific provisions of the MSWLF criteria, including variances from operating criteria in part 258 with respect to run-on controls (§ 258.26(a)(1)) and the liquids restrictions in § 258.28(a). In addition, the 2004 RD&D rule allows an additional variance for the final cover requirements set forth in the closure criteria in § 258.60(a)(1), (a)(2) and (b)(1). The 2004 RD&D rule limits the duration of the initial permit to three years, and the permit can be renewed for up to three additional 3-year terms, for a total of 12 years.

As of March 2014, in the most recent compilation of data available to the EPA, there were 30 active RD&D projects in 11 approved states and one project on tribal lands.[3] The maximum permit period for the first of these projects is coming to an end. This final rule allows the Director of an approved State to continue to extend the permit period for up to a total of 21 years to allow for continued research.

A. What did EPA propose?

EPA proposed this rulemaking through an action in the **Federal Register** published at 80 FR 70180, November 13, 2015. EPA proposed to allow the Director of an approved State to increase the maximum term for RD&D permits from 12 to 21 years at § 258.4(e)(1), in order to provide the EPA more time to continue to support research into the performance of bioreactors, alternative covers and run-on systems. In effect, the proposal would allow the Director of an approved State to increase the number of permit renewals from three to six. The EPA did not propose any other changes to the RD&D permit program and made it clear that EPA was not reopening at this time any other provision of the existing RD&D rule or MSWLF criteria in 40 CFR part 258.

Separately from this final rule, the EPA plans to publish an Advanced Notice of Proposed Rulemaking (ANPRM) seeking comment on the possibility of revising other sections of the MSWLF criteria (40 CFR part 258) to authorize the operation of wet landfills and bioreactors and other possible changes to the national criteria on a permanent basis. Interested parties will have an opportunity to comment on broader issues relating to bioreactor operation during the public comment period on that ANPRM.

In response to the 80 FR 70180, November 13, 2015 proposed rule, the Agency received six sets of comments during the comment period that closed on December 14, 2015. The six sets of comments were from: The States of Iowa, Kansas, Michigan and Nebraska; the Southeast Michigan Council of Governments, and the Solid Waste Disposal and Conversion Task Force of the Association of State and Territorial Solid Waste Management Officials. All comments can be reviewed on-line at *http://www.regulations.gov/,* using "EPA–HQ–RCRA–2015–0126" in the search box, and then by opening the docket folder and select 'view comments' to review any or all of the comments.

Five of the six commenters expressed support for extending maximum permit term for RD&D permits to EPA's proposed term of 21 years. Several commenters (including the one commenter that did not support an extension to 21 years) indicated support for eliminating the overall permit term entirely, arguing that any time limit may discourage entities from making investments. Several commenters also encouraged the EPA to establish a mechanism to convert RD&D permits into permanent designs and operational practices subject to appropriate monitoring and performance standards as administered by an approved state. Commenters indicated support for making permanent changes to the regulations at 40 CFR part 258 to authorize bioreactor operations.

After consideration of these comments, and in light of other information in the record, the EPA has decided to issue the final rule as proposed. The EPA disagrees with the comments that the RD&D permit program should not be time-limited, which is consistent with the EPA position since the original RD&D rule was promulgated in 2004. The RD&D permits have always been intended to be used for innovation and experimentation for a limited period of time. As such, the RD&D rule is not intended to authorize activities on a permanent basis, as unlimited renewals could effectively allow. In addition, EPA notes that the commenters did not suggest an alternative, discrete, maximum time frame other than EPA's proposal for a maximum permit term of 21 years.

The issue of making changes to the part 258 regulations to authorize bioreactor operations on a permanent basis is outside the scope of this rule, as EPA stated in the proposed rule (80 FR 70180, November 13, 2015). As discussed previously, EPA plans to publish an ANPRM requesting data relating to wet landfills and bioreactors. EPA intends this ANPRM to begin the process of considering additional changes to the part 258 regulations. In that proceeding, the commenters are free to raise concerns about how existing RD&D projects can be appropriately addressed under any potential future amendments to the existing MSWLF regulations. Thus, the comments did not change EPA's view that a maximum term of 21 years is an appropriate balance between allowing more time for continued research by EPA and allowing the facilities to continue operating for a significant but not open-ended period of time.

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[2] EPA began Project XL in 1995, and accepted projects until 2002, as a national pilot program to help business, state and local governments, and federal facilities work with EPA to develop and test innovative approaches to achieve better and more cost-effective environmental and public health protection. The provisions for the four Project XL landfills discussed here are codified in § 258.41.

[3] Permitting of Landfill Bioreactor Operations: Ten years After the RD&D Rule, EPA document number EPA/600/R–14/335.

B. Basis for This Final Rule

In the 2004 RD&D final rule, the EPA made clear its intention that MSWLF RD&D permits be of limited duration while also providing data to support future rulemaking. This final rule is intended to further these dual goals. Although the EPA does not expect that all RD&D permits will necessarily extend to the full permit term, the EPA believes that the current 12-year time limit may not be sufficient to realize potential benefits in all cases. Thus, extending the permit period for up to 21 years will provide more time to collect data on potential benefits and any problems without making the permit period so long as to be open-ended.

Extending the maximum permit term will help continuing efforts to collect data at existing RD&D units. If the EPA did not take this action, owners and operators using existing RD&D permits would need to make significant modifications to their disposal units or cease operation altogether, before reaching the end of their normal operations or closure. Because of the potential environmental benefits that may be derived from bioreactors, alternative cover designs, and run-on systems, the EPA believes that it is important to extend the maximum permit period to 21 years to provide more time to characterize the performance of RD&D projects without making the permit period so long as to be open-ended.

The EPA also wishes to enhance the economic feasibility to build and operate bioreactors or employ alternative approaches for final covers, which would provide additional sources of data in the future. The EPA has heard from stakeholders that limiting the permit period to 12 years has the unintended consequence of discouraging the development of bioreactors.

C. Implementation of This Final Rule

This rule does not require states with EPA-approved RD&D programs to modify their solid waste permit programs. Since this change to the 2004 RD&D rule provides more flexibility than existing federal criteria, states are not required to amend existing solid waste permit programs that have been determined by EPA to be adequate under 40 CFR part 239. At the same time, the RD&D rule (including the revised maximum permit term) is not self-implementing, and states are required to adopt the RD&D rule and obtain EPA approval for their RD&D program in order to issue a RD&D permit. States previously approved to issue RD&D permits that wish to increase the total length of time for which RD&D permits can be issued will need to notify the EPA in accordance with 40 CFR part 239. States with EPA-approved solid waste permit programs that have not previously sought approval for an RD&D program and now wish to do so will need to apply to EPA for approval of an RD&D program, including approval of the longer time period allowed by this rulemaking. Any state without an EPA-approved solid waste permit program may submit an application to EPA for a determination of adequacy under 40 CFR part 239 and may include a request for approval of the RD&D permit provisions reflecting the longer time period allowed by this rule. For MSWLF units located in Indian Country, EPA intends to consider the longer maximum permit term when issuing or modifying any site-specific RD&D rule. EPA has previously issued draft guidance on the site-specific flexibility request process in Indian Country. *See* "Site-Specific Flexibility Requests for Municipal Solid Waste Landfills in Indian Country," EPA 530–R–97–016, August 1997.

III. Statutory and Executive Orders Reviews

Additional information about these statutes and Executive Orders can be found at *http://www.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review.

B. Paperwork Reduction Act (PRA)

This action does not impose any new Information Collection Request (ICR) burden under the PRA. The purpose of this action is to extend the maximum allowable permit period for this program, and this change to the RD&D program itself does not impose any additional reporting requirements. The OMB has previously approved the information collection activities contained in the existing regulations in two different, applicable ICRs. The ICRs affected by this proposal are for 40 CFR part 239, Requirements for State Permit Program Determination of Adequacy and part 258, MSWLF Criteria. The OMB has reviewed the ICR for part 239 (ICR# 1608.07, OMB# 2050–0152). The EPA will request comments under the ICR review process from states that plan to make these revisions so that the EPA can better understand the expected burden that would be incurred by states who wish to make these changes. In addition, the EPA will also be requesting information from MSWLF owners/operators on the reporting burden that they would incur under an extended permit term provided in accordance with this rule under the part 258, MSWLF criteria ICR (ICR# 1381.09, OMB# 2050–0122) when that review process begins. This process is scheduled to be completed in June 2016.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, the impact of concern is any significant adverse economic impact on small entities. An agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, has no net burden or otherwise has a positive economic effect on the small entities subject to the rule. This rule will not create any additional burden for small entities. Small entities are not required to take any action as a consequence of this rule, and this action will not have a significant impact on a substantial number of small entities. We have therefore concluded that this action will have no net regulatory burden for all directly regulated small entities.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector. The costs involved in this action are imposed only by voluntary participation in a federal program.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175. The EPA has concluded that this action will have no new tribal implications, nor would it present any additional burden on the tribes. It will neither impose substantial direct compliance costs on tribal governments, nor preempt tribal law. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045, because it is not economically significant as defined in Executive Order 12866, and because the EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. The underlying RD&D rule requires all RD&D permits to include terms and conditions that are at least as protective as the criteria for municipal solid waste landfills to assure protection of human health and the environment, and this rule does not reopen or otherwise change that requirement.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes the human health and environmental risk addressed by this action will not have a new disproportionately high and adverse human health or environmental effects on minority, low-income or indigenous populations. The underlying RD&D regulations require all RD&D permits to include terms and conditions that are at least as protective as the criteria for municipal solid waste landfills to assure protection of human health and the environment. This final rule is an administrative action to extend the maximum permit period, and it does not reopen or otherwise change the requirement for protectiveness. Therefore, the EPA finds that the human health and environmental risks addressed by this action will not have disproportionately high and adverse human health or environmental effects on minority, low-income or indigenous populations, because this action does not affect the level of protection provided to human health or the environment.

K. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 258

Environmental protection, Municipal landfills, Reporting and recordkeeping requirements, Waste treatment and disposal.

Dated: April 29, 2016.

Gina McCarthy,

Administrator.

For the reasons set forth in the preamble, EPA amends 40 CFR part 258 as follows:

PART 258—CRITERIA FOR MUNICIPAL SOLID WASTE LANDFILLS

■ 1. The authority citation for part 258 continues to read as follows:

Authority: 33 U.S.C. 1345(d) and (e); 42 U.S.C. 6902(a), 6907, 6912(a), 6944, 6945(c) and 6949a(c), 6981(a).

Subpart A—General

■ 2. Revise § 258.4(e)(1) to read as follows:

§ 258.4 Research, development, and demonstration permits.

* * * * *

(e) * * *

(1) The total term for a permit for a project including renewals may not exceed twenty-one (21) years; and

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[FR Doc. 2016–10993 Filed 5–9–16; 8:45 am]

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DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 204, 209, 212, 227, 237, and 252

[Docket DARS–2014–0017]

RIN 0750–AH54

Defense Federal Acquisition Regulation Supplement: Disclosure to Litigation Support Contractors (DFARS Case 2012–D029)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is adopting as final, with changes, an interim rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to implement a section of the National Defense Authorization Act for Fiscal Year 2012 that provides DoD the authority to allow its litigation support contractors access to "sensitive information" subject to certain restrictions.

DATES: Effective May 10, 2016.

FOR FURTHER INFORMATION CONTACT: Ms. Amy G. Williams, telephone 571–372–6106.

SUPPLEMENTARY INFORMATION:

I. Background

DoD published an interim rule in the **Federal Register** at 79 FR 11337 on February 28, 2014, to implement section 802 of the National Defense Authorization Act for Fiscal Year 2012 (Pub. L. 112–81), which provides DoD the express authority to allow its litigation support contractors access to "sensitive information," provided that the litigation support contractor is subject to certain restrictions on using and disclosing such information. Two respondents submitted public comments in response to the interim rule.

II. Discussion and Analysis

DoD reviewed the public comments in the development of the final rule. A discussion of the comments received and the changes made to the rule as a result of those comments follows:

A. Summary of Significant Changes From the Interim Rule

1. A new paragraph (b)(4) is added to the provision at DFARS 252.204–7013 and a new paragraph (b)(5) is added to the clause at DFARS 252.204–7014 to clarify that the offeror and the contractor, respectively, shall destroy or return to the Government, at the request of the contracting officer, all litigation information in its possession upon completion of the authorized litigation support activities.

2. A new paragraph (b)(2) is added to the clause at DFARS 252.204–7014 to clarify that the contractor shall not disclose litigation information to any entity outside the contractor's organization unless, prior to disclosure, the contracting officer has provided written consent.

B. Analysis of Public Comments

1. Inclusion of Third Party Information

Comment: One respondent commented that the interim rule went beyond the definition of "sensitive information" provided in 10 U.S.C. 129d because, as implemented, "sensitive information" is not limited to information owned by the Department of Defense. The respondent suggested that the absence of the language "obtained from a person" as used in Exemption 4 of the Freedom of Information Act (5 U.S.C. 552(b)(4)) indicates that 10 U.S.C. 129d was intended to apply only to information "owned by the Department of Defense." The respondent stated that because the interim rule does not limit the scope of sensitive information to only information owned by DoD, the rule could expose the Government to liability or penalties for unauthorized disclosure of information under the Federal Tort Claims Act, or a taking of property under the U.S. Constitution, the Procurement Integrity Act, 41 U.S.C. 2101 *et seq.*, and the Trade Secrets Act, 18 U.S.C. 1905. The respondent called for rescission of the interim rule until the definition of "sensitive information" was narrowed.

Response: The statutory language and legislative history do not indicate that 10 U.S.C. 129d is limited only to information owned by the Department of Defense (or the U.S. Government). Prior to, and notwithstanding, the enactment of the statute, DoD was authorized to disclose information that it owns. 10 U.S.C. 129d authorizes disclosure of "sensitive information," without limitation related to the ownership or source of the information, for the sole purpose of providing litigation support to DoD. To narrow the definition as the respondent suggests would obviate the need for any statutory authorization. The new DFARS subpart 204.74 established by the interim rule implements the statutory authorization for litigation information, including sensitive information owned by or obtained from non-DoD sources. Disclosure of such information is thus authorized by law when done pursuant to DFARS subpart 204.74. No change is made in the final rule.

2. Safeguarding Unclassified Controlled Technical Information

Comment: One respondent questioned whether litigation support contractors, and their subcontractors, will be required to comply with the requirements at DFARS clause 252.204–7012, formerly entitled "Safeguarding of Unclassified Controlled Technical Information."

Response: The requirements of the clause at DFARS 252.204–7012, now entitled "Safeguarding Covered Defense Information and Cyber Incident Reporting," will apply to contractors, and their subcontractors, as required by the clause.

3. Disposition of Litigation Information

Comment: One respondent suggested that the interim rule should be amended to include requirements for the information provided to a litigation support contractor to be destroyed or returned to DoD when no longer needed or at the end of contract performance.

Response: Paragraph (b)(4) is added to the provision at DFARS 252.204–7013 and paragraph (b)(5) is added to the clause at DFARS 252.204–7014 to clarify that the contractor shall destroy or return to the Government, at the request of the contracting officer, all litigation information in its possession upon completion of the authorized litigation support activities.

4. Use of Litigation Information

Comment: One respondent suggested limiting the authorized use of litigation information to the litigation support required by the individual contract, under which the litigation information was received.

Response: Litigation support contractors must be able to use the litigation information provided by the Government as needed. A contractor may provide litigation support under multiple contracts. In such instances, limiting the scope of authorized use to only the contract under which the litigation information was provided could require the Government to provide the same information multiple times. Having to exchange and handle multiple copies of the same information increases the risk of inadvertent disclosure and the cost of performance and administration. No change is made in the final rule.

5. Third Party Beneficiary Rights

Comment: One respondent stated that if "sensitive information" includes information owned by third parties, then the interim rule should be amended to require litigation support contractors to comply with Federal Acquisition Regulation (FAR) 9.505–4(b) and have a direct nondisclosure agreement between the owner of the sensitive information and the litigation support contractor. The respondent also stated that the third party beneficiary rights are illusory without notice to the owner of the sensitive information.

Response: A direct nondisclosure agreement or prior notice requirement could prejudice the Government by providing premature warning of possible litigation or of the Government's litigation strategies. Accordingly, DoD has determined that requiring a direct nondisclosure agreement pursuant to FAR 9.505–4(b) for litigation support contractors would not be in the Government's interest. 10 U.S.C. 129d does not require that DoD confer upon an owner of sensitive information any third party beneficiary rights; however, at paragraph (d) of the clause at 252.204–7014, DoD has chosen to provide third party beneficiary rights analogous to those afforded by paragraph (c) of the clause at DFARS 252.227–7025. No change is made in the final rule as a result of this comment.

6. Appropriateness of an Interim Rule

Comment: One respondent stated that issuing an interim rule was not appropriate because there was inadequate justification for the determination of urgent or compelling reasons for doing so. The respondent suggested that, without further justification, a proposed rule was more appropriate and urged rescission of the interim rule.

Response: DoD published the basis for its determination that urgent and compelling reasons existed to authorize the use of an interim rule. After consideration of the respondent's comment, DoD determined that rescission of the interim rule was not warranted.

7. Release of Information to Litigation Support Subcontractors

Comment: One respondent stated that while litigation support contractors are required to flow down the clause at DFARS 252.204–7014 to subcontractors, it is not clear whether litigation support contractors and any subcontractors would be subject to DFARS clause 252.204–7000, Disclosure of Information.

Response: This rule does not affect the applicability of the clause DFARS at 252.204–7000. In accordance with its prescription at DFARS 204.404–70(a), the clause applies to all solicitations and contracts when the contractor will have access to or generate unclassified information that may be sensitive and inappropriate for release to the public. That clause will flow down to subcontracts, in accordance with paragraph (c) of the clause. There is no conflict between the DFARS 252.204–7000 clause and the DFARS 252.204–7014 clause, at the prime or subcontract level. The clause at DFARS 252.204–7000 prohibits the release of information outside the contractor's organization without permission from the contracting officer, while the DFARS 252.204–7014 clause requires the litigation support contractor to protect against any unauthorized releases of information, and does not authorize the contractor to make any releases outside the contractor's organization. However, to minimize any potential confusion, paragraph (b)(2) is added to the DFARS 252.204–7014 clause to state more clearly that it does not authorize the contractor to release litigation information outside the contractor's organization without permission of the contracting officer. Contracting officers, in conjunction with the Government litigation team, maintain control over the flow of information to litigation support contractors and outside parties.

8. Prescription Conflict

Comment: One respondent pointed out that the prescription in the interim rule at DFARS 204.7403(c) would have precluded DFARS 252.204–7015 from ever being included in a contract.

Response: This error was corrected in a technical amendment to the DFARS published in the **Federal Register** at 79 FR 13568 on March 11, 2014.

C. Other Changes

A summary of revisions made to the rule to make necessary conforming changes, clarifications, and editorial changes follows:

1. Definitions

a. The definition of "litigation information" is revised to clarify that information contained in publicly available solicitations will not be protected from disclosure as litigation information, because the information has already been released to the public. A corresponding policy statement is also added at DFARS 204.7402(c).

b. A policy statement is added at DFARS 204.7402(d) to state that contracting officers, when sharing sensitive information with a litigation support contractor, shall ensure that all other applicable requirements for handling and safeguarding the relevant types of sensitive information re included in the contract (*e.g.,* FAR subparts 4.4 and 24.1; DFARS subparts 204.4 and 224.1).

c. The definition of "litigation support contractor" is revised to clarify that, in addition to experts and technical consultants, the term also includes the contractor's subcontractors and suppliers. The text "the Department of Defense" is also removed, since the clause is only used in DoD contracts.

d. DFARS subpart 204.74, the provision at 252.204–7013, and the clauses at 252.204–7014 and 252.204–7015 are revised to include the full text of all relevant definitions, rather than cross-referencing the definitions that were provided in full-text only in the contract clause at DFARS 252.204–7014. Further, the definition of "sensitive information" is clarified by removing the term "confidential information" and replacing it with "controlled unclassified information" in subpart 204.74, the provision, and the clauses.

2. Conforming Changes

a. A conforming change has been made to DFARS 209.505–4(b)(i) in order to differentiate between the requirements that pertain to litigation support contractors from the requirements for other contractors, consistent with the changes in this rule.

b. DFARS 209.505–4(b)(ii) is added to clarify the policies and procedures (set forth in 204.74 and associated provisions and clauses) governing access to proprietary information for litigation support activities as an element of the coverage for organizational and consultant conflicts of interest.

3. Technical Clarifications

a. At paragraph (c)(2) of the provision at DFARS 252.204–7013 and at paragraph (d)(2) of the clause at DFARS 252.204–7014, the reference to "data or software" is changed to "litigation information" and the reference to "the unauthorized duplication, release or disclosure" is changed to "any such unauthorized use or disclosure," to more accurately refer to all of the unauthorized activities described at paragraph (c)(1) of the provision and paragraph (d)(1) of the clause.

b. The term "Solicitation" is removed from the title of the provision at DFARS 252.204–7013, as it is not necessary because the title already refers to "Offerors."

c. Paragraph (b) of the clause at DFARS 252.204–7014 is revised to state that the contractor "shall" instead of "agrees and acknowledges" to ensure the contractor complies with the limitations set forth in paragraph (b) during contract performance.

d. The title of the clause at DFARS 252.204–7015 is revised to "Notice of Authorized Disclosure of Information for Litigation Support" to more accurately depict the intent of the clause.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold and for Commercial Items, Including Commercially Available Off-the-Shelf Items

The prescriptions for use of the provision and clauses of this rule, which implement section 802 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2012 (Pub. L. 112–81) include use in contracts and subcontracts valued at or below the simplified acquisition threshold (SAT) and contracts and subcontracts for the acquisition of commercial items, including commercially available off-the-shelf (COTS) items.

A. Applicability to Contracts at or Below the SAT

41 U.S.C. 1905 governs the applicability of laws to contracts or subcontracts in amounts not greater than the SAT. It is intended to limit the applicability of laws to such contracts or subcontracts. 41 U.S.C. 1905 provides that if a provision of law contains criminal or civil penalties, or if the FAR Council makes a written determination that it is not in the best interest of the Federal Government to exempt contracts or subcontracts at or below the SAT, the law will apply to them. The Director, Defense Procurement and Acquisition Policy (DPAP), is the appropriate authority to make comparable determinations for regulations to be published in the DFARS, which is part of the FAR system of regulations.

DoD has determined that it is in the best interest of the Federal Government to apply the rule to contracts and subcontracts in amounts not greater than the SAT. Section 802 of the NDAA for FY 2012 was enacted to ensure DoD ligation support contractors protect sensitive information from any unauthorized disclosure and are prohibited from using such information for any purpose other than providing litigation support services to DoD. Based on data available in the Federal Procurement Data System (FPDS) for FY 2015, 421 of the 453 total DoD awards for professional attorney services or associated legal services were valued at less than the SAT. An exception for contracts valued at or under the SAT would exclude a large portion (93 percent) of the contracts intended to be covered by section 802, thereby undermining the overarching public policy purpose of the law and adversely affecting the Government's ability to successfully engage in legal proceedings.

B. Applicability to Contracts for the Acquisition of Commercial Items, Including COTS Items

41 U.S.C. 1906 governs the applicability of laws to contracts for the acquisition of commercial items, and is intended to limit the applicability of laws to contracts for the acquisition of commercial items. 41 U.S.C. 1906 provides that if a provision of law contains criminal or civil penalties, or if the FAR Council makes a written determination that it is not in the best interest of the Federal Government to exempt commercial item contracts, the provision of law will apply to contracts for the acquisition of commercial items. Likewise, 41 U.S.C. 1907 governs the applicability of laws to COTS items, with the Administrator for Federal Procurement Policy the decision authority to determine that it is in the best interest of the Government to apply a provision of law to acquisitions of COTS items in the FAR. The Director, DPAP, is the appropriate authority to make comparable determinations for regulations to be published in the DFARS, which is part of the FAR system of regulations.

Given that the requirements of section 802 of the NDAA for FY 2008 were enacted to protect sensitive information provided to DoD litigation support contractors from unauthorized use and disclosure, DoD has determined that it is in the best interest of the Federal Government to apply the rule to contracts for the acquisition of commercial items, as defined at FAR 2.101. Based on data available in FPDS for FY 2015, 352 of the 453 total DoD awards for legal support services were classified as commercial contracts. An exception for contracts for the acquisition of commercial items, would exclude 78 percent of the contracts intended to be covered by the law, thereby undermining the overarching public policy purpose of the law.

IV. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is a significant regulatory action and, therefore, was subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

V. Regulatory Flexibility Act

DoD does not expect this final rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* However, a final regulatory flexibility analysis has been prepared and is summarized as follows:

This rule amends the Defense Federal Acquisition Regulation Supplement (DFARS) to implement statutory authority (10 U.S.C. 129d) for DoD to allow its litigation support contractors to have access to "sensitive information," provided that the litigation support contractor is subject to certain restrictions on using and disclosing such information.

The objective of the rule is to expressly authorize DoD to provide its ligation support contractors with access to certain types of non-public information, provided that the ligation support contractors are required to protect that information from any unauthorized disclosure, and are prohibited from using that for any purpose other than providing litigation support services to DoD.

No significant issues were raised by the public comments in response to the initial regulatory flexibility analysis published with the interim rule.

According to data available in the Federal Procurement Data System for fiscal year 2015, DoD awarded 453 total contracts for legal support services to 212 unique vendors. Of those awards, 340 awards or 75 percent were made to 162 small businesses.

The rule imposes no reporting, recordkeeping, or other information collection requirements; rather, the rule subjects litigation support contractors to certain restrictions on using and disclosing litigation support information. DoD organizations using litigation support contractors are generally already using very restrictive nondisclosure agreements to govern any sensitive information that may be provided to, or developed or discovered by, the litigation support contractors in providing litigation support services for DoD. These DoD organizations will likely review their current practices and make any necessary modifications to ensure that there are no inconsistencies with the new requirements. As such, DoD does not expect the rule to have a significant economic impact on the small businesses affected by this rule.

There are no known significant alternatives to the rule. The impact of this rule on small business is not expected to be significant.

VI. Paperwork Reduction Act

The rule contains no new information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Parts 204, 209, 212, 227, 237, and 252

Government procurement.

Jennifer L. Hawes,
Editor, Defense Acquisition Regulations System.

Therefore, the interim rule amending 48 CFR parts 204, 212, 227, 237, and 252 which was published at 79 FR 11338 on February 28, 2014, is adopted as a final rule with the following changes:

■ 1. The authority citation for 48 CFR parts 204, 209, 212, and 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 204—ADMINISTRATIVE MATTERS

■ 2. Section 204.7401 is revised to read as follows:

204.7401 Definitions.

As used in this subpart—

Computer software means computer programs, source code, source code listings, object code listings, design details, algorithms, processes, flow charts, formulae, and related material that would enable the software to be reproduced, recreated, or recompiled. Computer software does not include computer data bases or computer software documentation.

Litigation information means any information, including sensitive information, that is furnished to the contractor by or on behalf of the Government, or that is generated or obtained by the contractor in the performance of litigation support under a contract. The term does not include information that is lawfully, publicly available without restriction, including information contained in a publicly available solicitation.

Litigation support means administrative, technical, or professional services provided in support of the Government during or in anticipation of litigation.

Litigation support contractor means a contractor (including its experts, technical consultants, subcontractors, and suppliers) providing litigation support under a contract that contains the clause at 252.204–7014, Limitations on the Use or Disclosure of Information by Litigation Support Contractors.

Sensitive information means controlled unclassified information of a commercial, financial, proprietary, or privileged nature. The term includes technical data and computer software, but does not include information that is lawfully, publicly available without restriction.

Technical data means recorded information, regardless of the form or method of the recording, of a scientific or technical nature (including computer software documentation). The term does not include computer software or data incidental to contract administration, such as financial and/or management information.

■ 3. Section 204.7402 is amended by adding paragraphs (c) and (d) to read as follows:

204.7402 Policy.

* * * * *

(c) Information that is publicly available without restriction, including publicly available solicitations for litigation support services, will not be protected from disclosure as litigation information.

(d) When sharing sensitive information with a litigation support contractor, contracting officers shall ensure that all other applicable requirements for handling and safeguarding the relevant types of sensitive information are included in the contract (*e.g.*, FAR subparts 4.4 and 24.1; DFARS subparts 204.4 and 224.1).

■ 4. Section 204.7403 is revised to read as follows:

204.7403 Solicitation provision and contract clauses.

(a) Use the provision at 252.204–7013, Limitations on the Use or Disclosure of Information by Litigation Support Offerors, in all solicitations for contracts that involve litigation support services, including solicitations using FAR part 12 procedures for the acquisition of commercial items.

(b) Use the clause at 252.204–7014, Limitations on the Use or Disclosure of Information by Litigation Support Contractors, in all solicitations and contracts that involve litigation support services, including solicitations and contracts using FAR part 12 procedures for the acquisition of commercial items.

(c) Use the clause at 252.204–7015, Notice of Authorized Disclosure of Information for Litigation Support, in all solicitations and contracts, including solicitations and contracts using FAR part 12 procedures for the acquisition of commercial items.

PART 209—CONTRACTOR QUALIFICATIONS

■ 5. Amend section 209.505–4 by—

■ a. Redesignating paragraph (b) as paragraph (b)(i);

■ b. In newly resdesignated paragraph (b)(i), removing "For contractors" and adding "For contractors, other than litigation support contractors," in its place; and

■ c. Adding new paragraph (b)(ii).

The addition reads as follows:

209.505–4 Obtaining access to proprietary information.

(b) * * *

(ii) For litigation support contractors accessing litigation information, including that originating from third parties, use and nondisclosure requirements are addressed through the use of the provision at 252.204–7013 and the clause at 252.204–7014, as prescribed at 204.7404(a) and 204.7404(b), respectively. Pursuant to that provision and clause, litigation support contractors are not required to enter into nondisclosure agreements directly with any third party asserting restrictions on any litigation information.

PART 212—SOLICITATION PROVISIONS AND CONTRACT CLAUSES FOR THE ACQUISITION OF COMMERCIAL ITEMS

212.301 [Amended]

■ 6. Amend section 212.301 by—

■ a. In paragraph (f)(ii)(E), removing the term "Solicitation"; and

■ b. In paragraph (f)(ii)(G), removing "Disclosure of Information to Litigation Support Contractors" and adding "Notice of Authorized Disclosure of Information for Litigation Support" in its place.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 7. Amend section 252.204–7013 by—

■ a. Revising the section heading.

■ b. In the clause heading, removing "Support Solicitation Offerors" and adding "Support Offerors" in its place;

■ c. Removing the clause date "(FEB 2014)" and adding "(MAY 2016)" in its place;

■ d. Revising paragraph (a).

■ e. In the paragraph (b) introductory text, adding "that" after "acknowledges";

■ f. In paragraph (b)(1), removing "That all" and adding "All" in its place;

■ g. In paragraph (b)(2), removing "That the" and adding "The" in its place;

■ h. In paragraph (b)(3), removing "That" and adding "The" in its place and removing "contracts." and adding "contracts; and" in its place;

■ i. Adding paragraph (b)(4); and

■ j. In paragraph (c)(2), removing "such data or software, for the unauthorized duplication, release, or disclosure" and adding "such litigation information, for any such unauthorized use or disclosure" in its place.

The revisions and addition read as follows:

252.204–7013 Limitations on the Use or Disclosure of Information by Litigation Support Offerors.

* * * * *

(a) *Definitions.* As used in this provision—

Computer software means computer programs, source code, source code listings, object code listings, design details, algorithms, processes, flow charts, formulae, and related material that would enable the software to be reproduced, recreated, or recompiled. Computer software does not include computer data bases or computer software documentation.

Litigation information means any information, including sensitive information, that is furnished to the contractor by or on behalf of the Government, or that is generated or obtained by the contractor in the performance of litigation support under a contract. The term does not include information that is lawfully, publicly available without restriction, including information contained in a publicly available solicitation.

Litigation support means administrative, technical, or professional services provided in support of the Government during or in anticipation of litigation.

Sensitive information means controlled unclassified information of a commercial, financial, proprietary, or privileged nature. The term includes technical data and computer software, but does not include information that is lawfully, publicly available without restriction.

Technical data means recorded information, regardless of the form or method of the recording, of a scientific or technical nature (including computer software documentation). The term does not include computer software or data incidental to contract administration, such as financial and/or management information.

(b) * * *

(4) Upon completion of the authorized litigation support activities, the Offeror will destroy or return to the Government at the request of the Contracting Officer all litigation information in its possession.

* * * * *

■ 8. Amend section 252.204–7014 by—

■ a. In the clause heading, removing the clause date "(FEB 2014)" and adding "(MAY 2016)" in its place;

■ b. In paragraph (a), revising the introductory text and the definitions of "Litigation information", "Litigation support contractor", and "Sensitive information";

■ c. Revising paragraph (b);

■ d. Redesignating paragraphs (c), (d), and (e) as paragraphs (d), (e), and (f);

■ e. Adding a new paragraph (c);

■ f. In newly redesignated paragraph (d)(2), removing "such data or software, for the unauthorized duplication, release, or disclosure" and adding "such litigation information, for any such unauthorized use or disclosure" in its place; and

■ g. In newly redesignated paragraph (f), removing "this paragraph (e)" and add "this paragraph (f)" in its place.

The revisions and addition read as follows:

252.204–7014 Limitations on the Use or Disclosure of Information by Litigation Support Contractors.

* * * * *

(a) *Definitions.* As used in this clause—

* * * * *

Litigation information means any information, including sensitive information, that is furnished to the contractor by or on behalf of the Government, or that is generated or obtained by the contractor in the performance of litigation support under a contract. The term does not include information that is lawfully, publicly available without restriction, including information contained in a publicly available solicitation.

* * * * *

Litigation support contractor means a contractor (including its experts, technical consultants, subcontractors, and suppliers) providing litigation support under a contract that contains this clause.

Sensitive information means controlled unclassified information of a commercial, financial, proprietary, or privileged nature. The term includes technical data and computer software, but does not include information that is lawfully, publicly available without restriction.

* * * * *

(b) *Limitations on use or disclosure of litigation information.* Notwithstanding any other provision of this contract, the Contractor shall—

(1) Access and use litigation information only for the purpose of providing litigation support under this contract;

(2) Not disclose litigation information to any entity outside the Contractor's organization unless, prior to such disclosure the Contracting Officer has provided written consent to such disclosure;

(3) Take all precautions necessary to prevent unauthorized disclosure of litigation information;

(4) Not use litigation information to compete against a third party for Government or nongovernment contracts; and

(5) Upon completion of the authorized litigation support activities, destroy or return to the Government at the request of the Contracting Officer all litigation information in its possession.

(c) Violation of paragraph (b)(1),(b)(2), (b)(3), (b)(4), or (b)(5) of this clause is a basis for the Government to terminate this contract.

* * * * *

■ 9. Amend section 252.204–7015 by—

■ a. Revising the section heading, introductory text, the clause heading, and paragraph (a); and

■ b. In the paragraph (b) heading, removing "*Authorized disclosure*" and adding "*Notice of authorized disclosures*" in its place.

The revision read as follows:

252.204–7015 Notice of Authorized Disclosure of Information for Litigation Support.

As prescribed in 204.7403(c), use the following clause:

Notice of Authorized Disclosure of Information for Litigation Support (May 2016)

(a) *Definitions.* As used in this clause—

Computer software means computer programs, source code, source code listings, object code listings, design details, algorithms, processes, flow charts, formulae, and related material that would enable the software to be reproduced, recreated, or recompiled. Computer software does not include computer data bases or computer software documentation.

Litigation support means administrative, technical, or professional services provided in support of the Government during or in anticipation of litigation.

Litigation support contractor means a contractor (including its experts, technical consultants, subcontractors, and suppliers) providing litigation support under a contract that contains the clause at 252.204–7014, Limitations on the Use or Disclosure of Information by Litigation Support Contractors.

Sensitive information means controlled unclassified information of a commercial, financial, proprietary, or privileged nature. The term includes technical data and computer software, but does not include information that is lawfully, publicly available without restriction.

Technical data means recorded information, regardless of the form or method of the recording, of a scientific or technical nature (including computer software documentation). The term does not include computer software or data incidental to contract administration, such as financial and/or management information.

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DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 212, 215, 216, and 225

Defense Federal Acquisition Regulation Supplement; Technical Amendments

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is making technical amendments to the Defense Federal Acquisition Regulation Supplement (DFARS) to provide needed editorial changes.

DATES: Effective May 10, 2016.

FOR FURTHER INFORMATION CONTACT: Ms. Jennifer L. Hawes, Defense Acquisition Regulations System, OUSD(AT&L)DPAP(DARS), Room

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Washington, DC 20301–3060.
Telephone 571–372–6115; facsimile
571–372–6094.

SUPPLEMENTARY INFORMATION: This final rule amends the DFARS as follows—

1. Corrects cross references at DFARS 212.301(f)(xvi), Acquisition of Information Technology, in paragraphs (A) and (B);

2. Directs contracting officers to additional DFARS Procedures, Guidance, and Information (PGI) by adding a cross reference at DFARS 215.300 and updates the date of the Director, Defense Procurement and Acquisition Policy memorandum entitled "Department of Defense Source Selection Procedures";

3. Corrects a threshold at DFARS 215.408(3)(ii)(A)(*1*)(*i*) to reflect $750,000 in lieu of $700,000 that was inadvertently omitted in the inflation adjustment DFARS Case 2014–D025 published in the **Federal Register** at 80 FR 36903;

4. Adds DFARS section 216.104 to provide guidance concerning selection and negotiation of the most appropriate contract type and also directs contracting officers to additional PGI coverage.

5. Redesignates paragraphs within DFARS 225.7003–2 to add a new paragraph (b) to provide an internet link for more information on specialty metals restrictions and reporting of noncompliances.

List of Subjects in 48 CFR 212, 215, 216, and 225

Government procurement.

Jennifer L. Hawes,
Editor, Defense Acquisition Regulations System.

Therefore, 48 CFR parts 212, 215, 216, and 225 are amended as follows:

■ 1. The authority citation for 48 CFR parts 212, 215, 216, and 225 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 212—ACQUISITION OF COMMERCIAL ITEMS

212.301 [AMENDED]

■ 2. Amend section 212.301, in paragraphs (f)(xvi)(A) and (B), by removing "239.7603(a)" and "239.7603(b)" and adding "239.7604(a)" and "239.7604(b)" in each place, respectively.

PART 215—CONTRACTING BY NEGOTIATION

■ 3. Revise section 215.300 to read as follows:

215.300 Scope of subpart.

Contracting officers shall follow the principles and procedures in Director, Defense Procurement and Acquisition Policy memorandum dated April 1, 2016, entitled "Department of Defense Source Selection Procedures," when conducting negotiated, competitive acquisitions utilizing FAR part 15 procedures. See PGI 215.300.

215.408 [AMENDED]

■ 4. Amend section 215.408, in paragraph (3)(ii)(A)(*1*)(*i*), by removing "$700,000" and adding "$750,000" in its place.

PART 216—TYPES OF CONTRACTS

■ 5. Add section 216.104 to read as follows:

216.104 Factors in selecting contract type.

Contracting officers shall follow the principles and procedures in Director, Defense Procurement and Acquisition Policy memorandum dated April 1, 2016, entitled "Guidance on Using Incentive and Other Contract Types," when selecting and negotiating the most appropriate contract type for a given procurement. See PGI 216.104.

PART 225—FOREIGN ACQUISITION

■ 6. Amend section 225.7003–2 by—

■ a. Redesignating paragraphs (a) and (b) as (1) and (2), respectively;

■ b. Designating the introductory text as paragraph (a);

■ c. In the newly redesignated paragraph (1), redesignating paragraphs (1) through (6) as paragraphs (i) through (vi), respectively; and

■ d. Adding paragraph (b).

The addition reads as follows:

225.7003–2 Restrictions.

* * * * *

(b) For more information on specialty metals restrictions and reporting of noncompliances, see *http://www.acq.osd.mil/dpap/cpic/ic/restrictions_on_specialty_metals_10_usc_2533b.html.*

[FR Doc. 2016–10830 Filed 5–9–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Part 217

[Docket DARS–2015–0067]

RIN 0750–AI80

Defense Federal Acquisition Regulation Supplement: Multiyear Contract Requirements (DFARS Case 2015–D009)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to implement a section of the National Defense Authorization Act for Fiscal Year 2015 and a section of the Department of Defense Appropriations Act, 2015, which address various requirements for multiyear contracts.

DATES: Effective May 10, 2016.

FOR FURTHER INFORMATION CONTACT: Mr. Christopher Stiller, telephone 571–372–6176.

SUPPLEMENTARY INFORMATION:

I. Background

DoD published a proposed rule in the **Federal Register** at 80 FR 81499 on December 30, 2015, to amend the DFARS to implement section 816 of the National Defense Authorization Act for Fiscal Year 2015 (Pub. L. 113–291) and section 8010 of the Department of Defense Appropriations Act, 2015 (Division C, Title VIII of Pub. L. 113–235), which address various requirements for multiyear contracts. There were no public comments submitted in response to the proposed rule. There are no changes from the proposed rule made in the final rule.

II. Applicability to Contracts at or Below the Simplified Acquisition Threshold (SAT) and for Commercial Items, Including Commercially Available Off-the-Shelf (COTS) Items

This rule does not add any new provisions or clauses or impact any existing provisions or clauses.

III. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

IV. Regulatory Flexibility Act

A final regulatory flexibility analysis (FRFA) has been prepared consistent with the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* The FRFA is summarized as follows:

The purpose of this rule is to implement section 816 of the National Defense Authorization Act for Fiscal Year 2015 and section 8010 of the Department of Defense Appropriations Act, 2015, which address various requirements for multiyear contracts. The rule will amend the Defense Federal Acquisition Regulation Supplement to require the head of agency to—

- Provide written notice to the congressional defense committees at least 30 days before termination of any multiyear contract; and
- For defense acquisition programs specifically authorized by law to be carried out using multiyear authority, ensure the Secretary of Defense certifies to Congress certain conditions for the multiyear contract have been met no later than 30 days before entry into the contract.

No comments were received from the public regarding the initial regulatory flexibility analysis.

The rule is not expected to impact small entities, because the rule applies to multiyear contract authorities for specific major defense acquisition programs for which small entities would not have the capacity or infrastructure to fulfill or sustain. Small entities may perform under multiyear contracts as subcontractors; however, the rule invokes requirements that apply at the prime contract level.

This rule does not create any new reporting or recordkeeping requirements.

There are no known significant alternatives to the rule. The impact of this rule on small business is not expected to be significant because it only affects DoD internal operating procedures.

V. Paperwork Reduction Act

The rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Part 217

Government procurement.

Jennifer Hawes,

Editor, Defense Acquisition Regulations System.

Therefore, 48 CFR part 217 is amended as follows:

PART 217—SPECIAL CONTRACTING METHODS

■ 1. The authority citation for 48 CFR part 217 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

■ 2. Revise section 217.170(b) to read as follows:

217.170 General.

* * * * *

(b) The head of the agency must provide written notice to the congressional defense committees at least 30 days before termination of any multiyear contract (section 8010 of Division C, Title VIII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113–235) and similar sections in subsequent DoD appropriations acts).

* * * * *

■ 3. Amend section 217.172—
■ a. In paragraph (c), by removing "10 U.S.C. 2306b(i)(3)" and adding "10 U.S.C. 2306b(i)(1)" in its place;
■ b. In paragraph (e)(1), by removing the word "and";
■ c. In paragraph (e)(2), by removing the period and adding a semicolon in its place;
■ d. By adding paragraphs (e)(3), (4), and (5);
■ e. In paragraph (h) introductory text, by removing "under the authority described in paragraph (b) of this section:" and adding "for a defense acquisition program that has been specifically authorized by law to be carried out using multiyear contract authority:" in its place;
■ f. In paragraph (h)(2) introductory text, by removing "March 1 of the year in which the Secretary requests legislative authority to enter" and adding "30 days before entry" in its place and by removing "10 U.S.C. 2306b(i)(1)(A) through (G)" and adding "10 U.S.C. 2306b(i)(3)" in its place;
■ g. In paragraph (h)(2)(i)—
■ i. By removing "FAR 17.105" and adding "FAR 17.105–1" in its places;
■ ii. By adding a comma after "(5)"; and
■ iii. By removing "10 U.S.C. 2306b(i)(1)(A)" and adding "10 U.S.C. 2306b(i)(3)(A)" in its place;
■ h. In paragraph (h)(2)(ii), by removing "10 U.S.C. 2306b(i)(1)(B)" and adding "10 U.S.C. 2306b(i)(3)(B)" in its place;
■ i. In paragraph (h)(2)(iii), by removing "10 U.S.C. 2306b(i)(1)(C)" and adding "10 U.S.C. 2306b(i)(3)(C)" in its place;
■ j. In paragraph (h)(2)(iv), by removing "10 U.S.C. 2306b(i)(1)(D)" and adding "10 U.S.C. 2306b(i)(3)(D)" in its place;
■ k. In paragraph (h)(2)(v), by removing "10 U.S.C. 2306b(i)(1)(E)" and adding "10 U.S.C. 2306b(i)(3)(E)" in its place;
■ l. In paragraph (h)(2)(vi), by removing "10 U.S.C. 2306b(i)(1)(F)" and adding "10 U.S.C. 2306b(i)(3)(F)" in its place;
■ m. In paragraph (h)(2)(vii), by removing "10 U.S.C. 2306b(i)(1)(G)" and adding "10 U.S.C. 2306b(i)(3)(G)" in its place;
■ n. In paragraph (h)(3), by removing "10 U.S.C. 2306b(i)(4)(A)" and adding "10 U.S.C. 2306b(i)(5)(A)" in its place;
■ o. In paragraph (h)(4), by removing "10 U.S.C. 2306b(i)(4)(B)" and adding "10 U.S.C. 2306b(i)(5)(B)" in its place;
■ p. In paragraph (h)(5), by removing "10 U.S.C. 2306b(i)(5)" and adding "10 U.S.C. 2306b(i)(6)" in its place;
■ q. In paragraph (h)(6), by removing "10 U.S.C. 2306b(i)(6)" and adding "10 U.S.C. 2306b(i)(7)" in its place;
■ r. Removing paragraph (h)(7);
■ s. Redesignating paragraph (h)(8) as (h)(7); and
■ t. In newly redesignated paragraph (h)(7) introductory text, adding "(10 U.S.C. 2306b(i)(4))" after "law's specific savings requirement" before the period.

The additions read as follows:

217.172 Multiyear contracts for supplies.

* * * * *

(e) * * *

(3) Cancellation provisions in the contract do not include consideration of recurring manufacturing costs of the contractor associated with the production of unfunded units to be delivered under the contract;

(4) The contract provides that payments to the contractor under the contract shall not be made in advance of incurred costs on funded units; and

(5) The contract does not provide for a price adjustment based on a failure to award a follow-on contract (section 8010 of Division C, Title VIII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113–235) and similar sections in subsequent DoD appropriations acts).

* * * * *

[FR Doc. 2016–10823 Filed 5–9–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 225 and 252

[Docket DARS–2015–0052]

RIN 0750–AI76

Defense Federal Acquisition Regulation Supplement: Duty-Free Entry Threshold (DFARS 2015–D036)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to update the threshold for duty-free entry on foreign supplies that are not from qualifying countries.

DATES: Effective May 10, 2016.

FOR FURTHER INFORMATION CONTACT: Mr. Christopher Stiller, telephone 571–372–6176.

SUPPLEMENTARY INFORMATION:

I. Background

DoD published a proposed rule in the **Federal Register** at 80 FR 72672 on November 20, 2015, to revise DFARS 225.901(3), and the clause 252.225–7013, Duty-Free Entry, by updating the $200 threshold that was established on April 30, 2003, to $300. There were no public comments submitted in response to the proposed rule. There are no changes from the proposed rule made in the final rule.

II. Applicability to Contracts at or Below the Simplified Acquisition Threshold and for Commercial Items, Including Commercially Available Off-the-Shelf Items

This rule merely updates the threshold for duty-free entry on foreign supplies that are not qualifying country suppliers or eligible products under a trade agreement. The clause at DFARS 252.225–7013, Duty-Free Entry, which is prescribed for use in lieu of Federal Acquisition Regulation clause 52.225–8, may be used in acquisitions at or below the simplified acquisition threshold when the savings from waiving the duty is anticipated to be more than the administrative cost of waiving the duty. The clause is not prescribed for use in contracts for commercial items, including commercially available off-the-shelf items.

III. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

IV. Regulatory Flexibility Act

A final regulatory flexibility analysis (FRFA) has been prepared consistent with the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* The FRFA is summarized as follows:

The objective of this rule is to amend Defense Federal Acquisition Supplement (DFARS) subpart 225.9 and the clause at 252.225–7013, Duty-Free Entry, to update the threshold for duty-free entry on foreign supplies that are not from the qualifying countries.

No comments were received from the public regarding the initial regulatory analysis.

DoD does not expect this rule to have a significant economic impact on a substantial number of small entities because this rule only makes an upward inflationary adjustment of an administrative threshold, from $200 to $300, at DFARS 225.901(3) and the clause at DFARS 252.225–7013. The information requested in DFARS clause 252.225–7013 supplements the information requested in the Federal Acquisition Regulation clause at 52.225–10 and is required only if the contractor is requesting duty-free entry.

Current data indicates, on average, approximately 31,500 duty-free entry certificates on foreign supplies for DoD per year. DoD does not expect a change in the estimated duty-free entry processes because the change is consistent with the rate of inflation; therefore, small entities will not be materially affected by this rule.

This rule does not impose any additional reporting, recordkeeping, and other compliance requirements.

There are no known significant alternatives to the rule. The impact of this rule on small business is not expected to be significant.

V. Paperwork Reduction Act

The rule affects the information collection requirements in the clause at DFARS 252.225–7013, currently approved under OMB Control Number 0704–0229, entitled "Defense Federal Acquisition Regulation Supplement Part 225, Foreign Acquisition, and related clauses," in accordance with the Paperwork Reduction Act (44.U.S.C. chapter 35). The impact, however, is negligible, because this rule only makes an upward adjustment of the duty-free entry threshold from the $200 to $300, consistent with the rate of inflation.

List of Subjects in 48 CFR Parts 225 and 252

Government procurement.

Jennifer L. Hawes,

Editor, Defense Acquisition Regulations System.

Therefore, 48 CFR parts 225 and 252 are amended as follows:

■ 1. The authority citation for parts 225 and 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 225—FOREIGN ACQUISITION

225.901 [Amended]

■ 2. In section 225.901, amend paragraph (3) by removing "$200" and adding "$300" in its place.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

252.225–7013 [Amended]

■ 3. Amend section 252.225–7013 by—

■ a. Removing the clause date "(NOV 2014)" and adding "(MAY 2016)" in its place; and

■ b. Amending paragraph (b)(3) by removing "$200" and adding "$300" in its place.

[FR Doc. 2016–10826 Filed 5–9–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Part 239

[Docket DARS–2015–0046]

RIN 0750–AI72

Defense Federal Acquisition Regulation Supplement: Long-Haul Telecommunications (DFARS Case 2015–D023)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to add a definition of "long-haul telecommunications."

DATES: Effective May 10, 2016.

FOR FURTHER INFORMATION CONTACT: Mr. Christopher Stiller, telephone 571–372–6176.

SUPPLEMENTARY INFORMATION:

I. Background

DoD published a proposed rule in the **Federal Register** at 80 FR 72674 on November 20, 2015, to revise DFARS subpart 239.74 to add "long-haul telecommunications" to the telecommunications services definitions and identify Defense Information Systems Agency as the procurer of long-haul telecommunications services for DoD, as mentioned in DoD Directive 5105.19, Defense Information Systems Agency. There were no public comments submitted in response to the proposed rule. There are no changes from the proposed rule made in the final rule.

II. Applicability to Contracts at or Below the Simplified Acquisition Threshold and for Commercial Items, Including Commercially Available Off-the-Shelf Items

This case does not add any new provisions or clauses or impact any existing provisions or clauses.

III. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

IV. Regulatory Flexibility Act

A final regulatory flexibility analysis (FRFA) has been prepared consistent with the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* The FRFA is summarized as follows:

The purpose of this final rule is to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to add a definition of "long-haul telecommunications" and provide a pointer to DFARS Procedures, Guidance, and Information for procedures internal to DoD.

No comments were received from the public regarding the initial regulatory flexibility analysis.

The requirements under this rule will apply to long-haul telecommunications (Product Service Code D304) requirements as defined in the DoD Directive 5105.19, Defense Information Systems Agency. According to data available in the Federal Procurement Data System-Next Generation (FPDS–NG) for fiscal year 2014 through July 31, 2015, DoD awarded 13,596 new long-haul telecommunications contracts. Approximately 3 percent (451) of the total were awarded to small entities (comprised of 222 unique small entities).

This rule does not create any new reporting or recordkeeping requirements.

There are no known significant alternatives to the rule. The impact of this rule on small entities is not expected to be significant because it only affects DoD internal operating procedures.

V. Paperwork Reduction Act

The rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Part 239

Government procurement.

Jennifer L. Hawes,

Editor, Defense Acquisition Regulations System.

Therefore, 48 CFR part 239 is amended as follows:

PART 239—ACQUISITION OF INFORMATION TECHNOLOGY

■ 1. The authority citation for part 239 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

■ 2. Amend section 239.7401 by—

■ a. Removing the alphabetical paragraph designation from each definition; and

■ b. Adding, in alphabetical order, a new definition for "*Long-haul telecommunications*".

The addition reads as follows:

239.7401 Definitions.

* * * * *

Long-haul telecommunications means all general and special purpose long-distance telecommunications facilities and services (including commercial satellite services, terminal equipment and local circuitry supporting the long-haul service) to or from the post, camp, base, or station switch and/or main distribution frame (except for trunk lines to the first-serving commercial central office for local communications services).

* * * * *

■ 3. Amend section 239.7402 by adding paragraph (d) to read as follows:

239.7402 Policy.

* * * * *

(d) *Long-haul telecommunications services.* When there is a requirement for procurement of long-haul telecommunications services, follow PGI 239.7402(d).

[FR Doc. 2016–10825 Filed 5–9–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Part 241

[Docket DARS–2015–0050]

RIN 0750–AI74

Defense Federal Acquisition Regulation Supplement: Contract Term Limit for Energy Savings Contracts (DFARS Case 2015–D018)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to clarify the contract term for energy savings contracts awarded under 10 U.S.C. 2913.

DATES: Effective May 10, 2016.

FOR FURTHER INFORMATION CONTACT: Ms. Amy Williams, telephone 571–372–6106.

SUPPLEMENTARY INFORMATION:

I. Background

DoD published a proposed rule in the **Federal Register** at 80 FR 72675 on November 20, 2015, to clarify the contract term for contracts awarded under the statutory authority of 10 U.S.C. 2913. Ten respondents submitted public comments in response to the proposed rule.

II. Discussion and Analysis

DoD reviewed the public comments in the development of the final rule. A discussion of the comments received and the changes made to the rule as a result of those comments follows:

A. Summary of Significant Changes From the Proposed Rule

The final rule has been revised at DFARS 241.103(2) to provide that the contracting officer may enter into an energy savings contract under 10 U.S.C. 2913 for a period not to exceed 25 years. This change to "energy savings contract" from "shared energy savings contract" brings the term limit for all activities authorized by section 2913 under the final rule.

B. Analysis of Public Comments

1. General Support for the Rule

Comment: Several respondents expressed support for the changes in the proposed rule, indicating that the term limit of 25 years would promote the use of shared energy savings contracts, have a positive benefit on small businesses, facilitate greater partnerships between utilities and DoD customers, and increase competition. One respondent indicated that the term limit of 25 years would lead to several benefits including deeper retrofits, elimination of cream skimming, effectively leveraging private sector funding, and accomplishing the President's Performance Contracting Challenge goals.

Response: Noted.

2. Clarification of the Contract Period

Comment: One respondent requested clarification of the date that the contract period commences. The respondent stated that the rule would most effectively accomplish its goal of accommodating project financing needs if the contract period were tied to the payment term, and suggested that the rule be revised to state the following: "The contracting officer may enter into a shared energy savings contract under 10 U.S.C. 2913 for a 'payment term' not to exceed 25 years."

Response: Payment term is interpreted as the performance period of the contract, which is not to exceed 25 years. The contract period will include the entire performance period, including construction, if any.

3. Inclusion of Water-Related Projects

Comment: One respondent expressed concern that the rule's failure to address water-related projects authorized by 10 U.S.C. 2866 would result in ambiguity and confusion with regard to the term limit for such contracts. The respondent suggested that the rule be revised to state the following: "The contracting officer may enter into a contract under 10 U.S.C. 2913 or 10 U.S.C. 2866 for a period not to exceed 25 years."

Response: The recommendation is beyond the scope of the case.

4. Application of 10 U.S.C. 2913 to Agreements With Gas or Electric Utilities

Comment: One respondent stated that 10 U.S.C. 2913 applies not only to shared energy savings contracts, but also to agreements with gas or electric companies, and recommended removing the reference to shared energy savings contracts.

Response: The final rule has been revised at 241.103(2) to provide that the contracting officer may enter into an energy savings contract under 10 U.S.C. 2913 for a period not to exceed 25 years.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold and for Commercial Items, Including Commercially Available Off-the-Shelf Items

This rule does not add any new provisions or clauses or impact any existing provisions or clauses.

IV. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

V. Regulatory Flexibility Act

A final regulatory flexibility analysis (FRFA) has been prepared consistent with the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* The FRFA is summarized as follows:

This final rule amends the Defense Federal Acquisition Regulation Supplement (DFARS) to clarify the contract term for contracts awarded under the statutory authority of 10 U.S.C. 2913. Section 2913 requires DoD to develop a simplified method of contracting for shared energy savings contract services that will accelerate the use of such contracts. DoD is authorized by section 2913 to contract with utility service providers to implement energy conservation measures on military bases. Section 2913 does not indicate a term limit for contracts or activities executed under this authority, and this has created ambiguity and inconsistency throughout DoD on the term limit that is imposed on contracts awarded under the authority. Additionally, the ambiguity has resulted in a hesitation to enter shared energy savings contracts, contrary to the intent of section 2913.

No comments were received from the public regarding the initial regulatory flexibility analysis.

The rule is not anticipated to have a significant economic impact on small business entities. The number of contract awards made under the authority of 10 U.S.C. 2913 is not currently tracked by DoD's business systems. However, it is estimated that approximately 25 shared energy savings projects are initiated across DoD each year, with approximately 17 being awarded annually. It is believed that most awards are made to large utility providers, with generally 25% or more of the renovation and operations and maintenance work executed under the awards being subcontracted to local small business by the utility provider.

This rule does not create any new reporting or recordkeeping requirements.

There are no known significant alternatives to the rule.

VI. Paperwork Reduction Act

The rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Part 241

Government procurement.

Jennifer L. Hawes,
Editor, Defense Acquisition Regulations System.

Therefore, 48 CFR part 241 is amended as follows:

PART 241—ACQUISITION OF UTILITY SERVICES

■ 1. The authority citation for part 241 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

■ 2. Amend section 241.103 by—
■ a. Redesignating paragraphs (2) and (3) as paragraphs (3) and (4); and
■ b. Adding a new paragraph (2).

The addition reads as follows:

241.103 Statutory and delegated authority.

* * * * *

(2) The contracting officer may enter into an energy savings contract under 10 U.S.C. 2913 for a period not to exceed 25 years.

* * * * *

[FR Doc. 2016–10824 Filed 5–9–16; 8:45 am]

BILLING CODE 5001–06–P

Proposed Rules

Federal Register
Vol. 81, No. 90
Tuesday, May 10, 2016

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF ENERGY

5 CFR Chapter XXIII

10 CFR Chapters II, III, and X

Reducing Regulatory Burden

AGENCY: Office of the General Counsel, Department of Energy.

ACTION: Request for information (RFI).

SUMMARY: As part of its implementation of Executive Order 13563, "Improving Regulation and Regulatory Review," issued by the President on January 18, 2011, the Department of Energy (Department or DOE) is seeking comments and information from interested parties to assist DOE in reviewing its existing regulations to determine whether any such regulations should be modified, streamlined, expanded, or repealed. The purpose of DOE's review is to make the agency's regulatory program more effective and less burdensome in achieving its regulatory objectives. In this request for information, DOE also highlights its most recent regulatory review and reform efforts conducted to date in light of comments from interested parties.

DATES: Written comments and information are requested on or before July 11, 2016.

ADDRESSES: Interested persons are encouraged to submit comments, identified by "Regulatory Burden RFI," by any of the following methods:

White House Web site: http://www.whitehouse.gov/engage.

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Email: Regulatory.Review@hq.doe.gov. Include "Regulatory Burden RFI" in the subject line of the message.

Mail: U.S. Department of Energy, Office of the General Counsel, 1000 Independence Avenue SW., Room 6A245, Washington, DC 20585.

Docket: For access to the docket to read background documents, or comments received, go to the Federal eRulemaking Portal at *http://www.regulations.gov.*

The Department's plan for retrospective review of its regulations and its subsequent update reports can be accessed at *http://energy.gov/gc/services/open-government/restrospective-regulatory-review.*

FOR FURTHER INFORMATION CONTACT: Matthew Zogby, Office of the Assistant General Counsel for Legislation, Regulation, and Energy Efficiency, U.S. Department of Energy, Office of the General Counsel, 1000 Independence Avenue SW., Washington, DC 20585. Email: *Regulatory.Review@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: On January 18, 2011, the President issued Executive Order 13563, "Improving Regulation and Regulatory Review," to ensure that Federal regulations seek more affordable, less intrusive means to achieve policy goals, and that agencies give careful consideration to the benefits and costs of those regulations. To that end, the Executive order requires, among other things, that:

- Agencies propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs; and that agencies tailor regulations to impose the least burden on society, consistent with obtaining the regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations; and that, consistent with applicable law, agencies select, in choosing among alternative regulatory approaches, those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity).
- The regulatory process encourages public participation and an open exchange of views, with an opportunity for the public to comment.
- Agencies coordinate, simplify, and harmonize regulations to reduce costs and promote certainty for businesses and the public.
- Agencies consider low-cost approaches that reduce burdens and maintain flexibility.
- Regulations be guided by objective scientific evidence.

Additionally, the Executive Order directs agencies to consider how best to promote retrospective analyses of existing rules. Specifically, agencies were required to develop a plan under which the agency will periodically review existing regulations to determine which should be maintained, modified, strengthened, or repealed to increase the effectiveness and decrease the burdens of the agency's regulatory program. DOE's plan and its subsequent update reports can be accessed at *http://energy.gov/gc/services/open-government/restrospective-regulatory-review.*

The Department is committed to maintaining a consistent culture of retrospective review and analysis. DOE will continually engage in review of its rules to determine whether there are burdens on the public that can be avoided by amending or rescinding existing requirements. To that end, DOE is publishing this RFI to again explicitly solicit public input. In addition, DOE is always open to receiving information about the impact of its regulations. To facilitate both this RFI and the ongoing submission of comments, interested parties can identify regulations that may be in need of review at the following White House Web site: *http://www.whitehouse.gov/engage.* DOE has also created a link on the Web page of DOE's Office of the General Counsel to an email in-box for the submission of comments, *Regulatory.Review@hq.doe.gov.*

While the Department promulgates rules in accordance with the law and to the best of its analytic capability, it is difficult to be certain of the consequences of a rule, including its costs and benefits, until it has been tested. Because knowledge about the full effects of a rule is widely dispersed in society, members of the public are likely to have useful information and perspectives on the benefits and burdens of existing requirements and how regulatory obligations may be updated, streamlined, revised, or repealed to better achieve regulatory objectives, while minimizing regulatory burdens. Interested parties may also be well-positioned to identify those rules that are most in need of review and, thus, assist the Department in prioritizing and properly tailoring its retrospective review process. In short, engaging the public in an open, transparent process is a crucial step in DOE's review of its existing regulations.

The Department's dedication to involve the public in the regulatory process includes a number of ongoing successful public engagement efforts. These efforts include seeking public input on the retrospective review process, posting comments on our Web page to encourage the public to share their thoughts on the comments of others, and considering input received through a dedicated retrospective review email address. These efforts encourage public engagement in the retrospective review process, and provide the ability for the public to comment and engage in a dialog on the improvement of DOE regulations.

The Department has developed another innovative way to engage the public in the regulatory review process. The Department has tasked the Appliance Standards and Rulemaking Federal Advisory Committee (ASRAC) to assist DOE in the retrospective review process. ASRAC was created as an advisory committee to provide advice and recommendations on the development of standards and test procedures for residential appliances and commercial equipment, certification and enforcement of standards, and product labeling. ASRAC is comprised of representatives from industry, utilities, energy efficiency/environmental advocacy groups, and consumer groups. As a part of the retrospective regulatory review process, the Department has tasked ASRAC to identify particular rules for which revision would have the most positive impact and potential improvement to the regulatory process. ASRAC meetings are also open to the public and notice of ASRAC meetings are published in the **Federal Register**. ASRAC has also been tasked with writing a report that details their recommendations for the regulatory review process. ASRAC held two meetings at which retrospective regulatory review was on the agenda. Involving ASRAC in the regulatory review process will provide the public with another means to help the Department determine the regulations that could benefit the most from retrospective review.

Department of Energy Retrospective Review Successes

The Department highlights the examples below as retrospective review successes resulting from public engagement in the regulatory process. For further details and additional examples, the public is invited to review DOE's previous update reports, available at *http://www.energy.gov/gc/services/open-government/restrospective-regulatory-review*. New retrospective successes from DOE's March 2016 and July 2015 reports are described below.

(1) DOE published a proposed rule to amend its regulations for the timely coordination of Federal Authorizations for proposed interstate electric transmission facilities pursuant to section 216(h) of the Federal Power Act. This rulemaking will improve the pre-application procedures and result in more efficient processing of applications. The proposed rule implements a number of Presidential directives, including the Presidential Memorandum on "Speeding Infrastructure Development through More Efficient and Effective Permitting and Environmental Review" (August 31, 2011), Executive Order 13604, "Improving Performance of Federal Permitting and Review of Infrastructure Projects" (March 22, 2012), the Presidential Memorandum on "Modernizing Federal Infrastructure Review and Permitting Regulations, Policies, and Procedures " (May 17, 2013, and the Presidential Memorandum on "Transforming our Nation's Electric Grid Through Improved Siting, Permitting, and Review" (June 7, 2013).

(2) DOE published a final rule amending the administrative requirements for grants and cooperative agreements with for-profit organizations. Specifically, the rule modifies title provisions and requirements related to the handling of real property and equipment acquired with federal funds. The rule also adds provisions related to export control requirements and supporting U.S. manufacturing, reporting on utilization of subject inventions, novation of financial assistance agreements, and changes of control of recipients. The rule will reduce the burden on grant recipients because they will need to file only UCC–1s and will not have to negotiate a separate "priority" term in their individual grant agreements. As part of its retrospective review efforts, DOE will continue to consider input from affected parties on ways to reduce burdens on its grant recipients and entities with which DOE enters cooperative agreements.

(3) DOE issued a comprehensive update of regulations in 10 CFR part 810 concerning Assistance to Foreign Atomic Energy Activities, making the regulations consistent with current global civil nuclear trade practices and nonproliferation norms. DOE has also initiated a process improvement program to reduce the public burden associated with nuclear technology export authorizations, to reduce specific authorization processing time, and to create a guide to part 810 and an electronic application and tracking (e-810) system. Since the Part 810 final rule went into effect on March 25, 2015, DOE has created guidance and FAQs, which are available online. As a result of the rule revisions, DOE estimates a net benefit, for the period 2013–2030, of $19,896,142 per year at a 7-percent discount rate and $19,253,076 per year at a 3-percent discount rate. The process improvement program is expected to reduce the time needed for DOE to process nuclear export authorizations and provide more transparency to submitters regarding process steps and the associated time needed to complete each step.

List of Questions for Commenters

The following list of questions is intended to assist in the formulation of comments and not to restrict the issues that may be addressed. In addressing these questions or others, DOE requests that commenters identify with specificity the regulation or reporting requirement at issue, providing legal citation where available. The Department also requests that the submitter provide, in as much detail as possible, an explanation why a regulation or reporting requirement should be modified, streamlined, expanded, or repealed, as well as specific suggestions of ways the Department can better achieve its regulatory objectives.

(1) How can the Department best promote meaningful periodic reviews of its existing rules and how can it best identify those rules that might be modified, streamlined, expanded, or repealed?

(2) What factors should the agency consider in selecting and prioritizing rules and reporting requirements for review?

(3) Are there regulations that are or have become unnecessary, ineffective, or ill advised and, if so, what are they? Are there rules that can simply be repealed without impairing the Department's regulatory programs and, if so, what are they?

(4) Are there rules or reporting requirements that have become outdated and, if so, how can they be modernized to accomplish their regulatory objectives better?

(5) Are there rules that are still necessary, but have not operated as well as expected such that a modified, stronger, or slightly different approach is justified?

(6) Does the Department currently collect information that it does not need or use effectively to achieve regulatory objectives?

(7) Are there regulations, reporting requirements, or regulatory processes that are unnecessarily complicated or could be streamlined to achieve regulatory objectives in more efficient ways?

(8) Are there rules or reporting requirements that have been overtaken by technological developments? Can new technologies be leveraged to modify, streamline, or do away with existing regulatory or reporting requirements?

(9) How can the Department best obtain and consider accurate, objective information and data about the costs, burdens, and benefits of existing regulations? Are there existing sources of data the Department can use to evaluate the post-promulgation effects of regulations over time? We invite interested parties to provide data that may be in their possession that documents the costs, burdens, and benefits of existing requirements.

(10) Are there regulations that are working well that can be expanded or used as a model to fill gaps in other DOE regulatory programs?

The Department notes that this RFI is issued solely for information and program-planning purposes. Responses to this RFI do not bind DOE to any further actions related to the response. All submissions will be made publically available on *http://www.regulations.gov.*

Issued in Washington, DC on May 3, 2016.

Steven P. Croley,

General Counsel.

[FR Doc. 2016–10956 Filed 5–9–16; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Parts 272, 274, and 280

[FNS 2015–0021]

RIN 0584–AE00

Supplemental Nutrition Assistance Program (SNAP): Disaster Supplemental Nutrition Assistance Program (D–SNAP)

AGENCY: Food and Nutrition Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would amend the Supplemental Nutrition Assistance Program (SNAP) (formerly the Food Stamp Program) regulations to establish procedures for planning, requesting and operating a Disaster Supplemental Nutrition Assistance Program (D–SNAP). The rulemaking is necessary to implement a section of the Food and Nutrition Act of 2008. This rulemaking also addresses a section of the Robert T. Stafford Disaster Relief and Emergency Assistance Act of 1988 and accompanying Executive Order 12673, which provides the authority for the Department to determine the need for SNAP assistance during a presidentially-declared disaster.

DATES: Written comments on this proposed rule must be received on or before July 11, 2016.

ADDRESSES: The Food and Nutrition Service (FNS) invites interested persons to submit comments on this proposed rule. Comments may be submitted by any of the following methods:

Federal eRulemaking Portal: Preferred method. Go to *http://www.regulations.gov;* follow the online instructions for submitting comments on Docket FNS 2015–0021.

FAX: Submit comments by facsimile transmission to (703) 305–2486, attention: Sasha Gersten-Paal.

Mail: Send comments to Sasha Gersten-Paal, Branch Chief, Certification Policy Branch, Program Development Division, Supplemental Nutrition Assistance Program, Food and Nutrition Service, 3101 Park Center Drive, Room 812, Alexandria, Virginia, 22302, (703) 305–2507.

Hand Delivery or Courier: Deliver comments to Sasha Gersten-Paal at the above address.

Additional electronic filing information: You may download a copy of this rule from *www.fns.usda.gov/SNAP.* You may also comment via the Internet at the same address. Please include ATTENTION RIN: 0584–AE00 in the subject line and your name and address in the message. If you do not receive a confirmation that we have received your comment please call Sasha Gersten-Paal at 703–305–2507.

All comments on this proposed rule will be included in the record and will be made available to the public. Please be advised that the substance of the comments and the identity of the individuals or entities submitting the comments will be subject to public disclosure. FNS will make the comments publicly available on the Internet via *http://www.regulations.gov.*

All submissions will be available for public inspection at the office of FNS during regular business hours (8:30 a.m. to 5:00 p.m., Monday through Friday) at 3101 Park Center Drive, Room 810, Alexandria, Virginia 22302–1594.

Written comments on this proposed rule should be specific, confined to issues pertinent to the rule, and should explain the reason for any change you recommend. Where possible, you should reference the specific section or paragraph you are addressing. We may not consider or include in the Administrative Record that supports the final rulemaking comments that we receive after the close of the comment period or comments delivered to an address other than that listed above. We will make available all comments for public inspection, including, name, address and other contact information of respondents. If you wish to request that we consider withholding your name, address, or other contact information from public review or from disclosure under the Freedom of Information Act, you must state this prominently at the beginning of your comment. We will honor requests for confidentiality on a case-by-case basis to the extent allowed by law. We will make available for public inspection in their entirety all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses.

FOR FURTHER INFORMATION CONTACT: For further information concerning this Notice of Proposed Rulemaking (NPRM) you may contact Sasha Gersten-Paal, Branch Chief, Certification Policy Branch, Program Development Division, Supplemental Nutrition Assistance Program, 3101 Park Center Drive, Room 810, Alexandria, Virginia, 22302, or by email at *Sasha.Gersten-Paal@fns.usda.gov.*

SUPPLEMENTARY INFORMATION:

Background

The basic premise underlying the D–SNAP and this proposed rule is that when a disaster occurs (and after commercial channels of food distribution are operating again) there is an increased and immediate need for nutrition assistance for families that have suffered loss of income and/or incurred additional costs due to the disaster. SNAP is not designed to take disaster-related expenses into account in determining eligibility. SNAP eligibility requirements typically do not match the sudden (but temporary) needs of households affected by disaster, and SNAP's procedural requirements make it difficult for States to handle the large number of people suddenly in need of immediate assistance. Thus, it may be necessary to implement a D–SNAP that uses a different set of rules to determine need and issue benefits.

How D–SNAP Currently Operates

D–SNAP provides temporary food assistance for households affected by a disaster when there is a Presidential disaster declaration that includes the provision of individual assistance. Currently, D–SNAP provides one month of benefits to eligible disaster survivors and can facilitate the issuance of supplemental SNAP benefits for currently certified households. To be eligible for D–SNAP, a household must live (or in some cases, work) in the identified disaster area, have been affected by the disaster, and meet certain D–SNAP eligibility criteria. D–SNAP is designed for situations where a large number of households have disaster-related expenses not contemplated when an individual applies for SNAP.

The primary responsibility for providing emergency food assistance rests with the State agency. Currently, utilizing FNS Guidance, State agencies design their own D–SNAP Plan, evaluate the need for a D–SNAP or another feeding program should a disaster strike, submit to FNS a detailed request to operate a D–SNAP, effectively implement the D–SNAP, ensure program integrity in D–SNAP operations, submit daily reports, perform post-disaster reviews and report their findings to FNS.

What acronyms or abbreviations are used in this supplementary discussion of the proposed provisions?

In the discussion of the proposed provisions in this rule, we use the following acronyms or other abbreviations to stand in for certain words or phrases:

Phrase	Acronym, abbreviation, or symbol
Code of Federal Regulations	CFR.
United States Code	U.S.C.
Disaster Supplemental Nutrition Assistance Program	D–SNAP.
Electronic Benefit Transfer	EBT.
Individual Assistance	IA.
Federal Register	FR.
Federal Fiscal Year	FY.
Food and Nutrition Act of 2008	Act.
Food and Nutrition Service	FNS.
Secretary of Agriculture	the Secretary.
Supplemental Nutrition Assistance Program	SNAP.
U. S. Department of Agriculture	the Department.
Robert T. Stafford Disaster Relief and Emergency Assistance Act	Stafford Act.
Federal Emergency Management Agency	FEMA.

Legislation and Regulations

What authorities does the Department have regarding disasters?

FNS can provide disaster nutrition assistance in three ways:

- Provide USDA purchased foods for shelters and other mass feeding sites (42 U.S.C. 5180);
- Provide USDA commodity (food) assistance for distribution directly to households in need in certain limited circumstances (42 U.S.C.5180);
- Approve a State D–SNAP operation and provide funding for 100 percent of disaster benefits and 50 percent of State administrative costs. FNS supports the State's efforts to provide D–SNAP benefits by providing policy guidance, training, and technical assistance to State agencies as they plan, implement, and assess their D–SNAP activities (42 U.S.C. 5179).

All three types of assistance may be needed for disaster victims throughout or at different points of time following the disaster. However, households cannot simultaneously receive both D–SNAP benefits and commodity assistance.

Under the Stafford Act the President is authorized to declare a "major disaster" when requested to do so by the Governor of a state stuck by a natural disaster. The President may direct Federal agencies to support States' response efforts and assist in the distribution of food and other consumable supplies.

After consultation with FEMA, the Secretary also has the authority to establish temporary emergency standards of eligibility for victims of a disaster if they are in need of temporary food assistance, and commercial channels of food distribution were disrupted, but have again become available. FNS has generally approved States' requests for D–SNAP under Stafford Act authority when areas affected by disasters have received a Presidential disaster declaration that includes an individual assistance declaration, since this establishes the need for assistance at the household level.

What does legislation say about D–SNAP?

The Stafford Act provides the Secretary of Agriculture with the authority to operate a D–SNAP when affected areas have received a Presidential major disaster declaration for individual assistance (IA) and when commercial channels of food distribution are available. Section (5)(h) of the Act provides the Secretary with the authority to establish temporary emergency standards of eligibility for households who are survivors of a disaster that disrupts commercial channels of food distribution, after those channels have been restored. The Act requires that the Secretary establish a disaster task force to assist States in the implementation and operation of a D–SNAP and send members to the disaster site if cost-effective. The Act also requires that the regulations address replacement benefits for households currently certified in SNAP that experience food loss, and provides for the adjustment of issuance and reporting requirements in the D–SNAP.

Under Section 11(e)(14) of the Act, as part of a State agency's overall Plan of Operation, the State agency is required to specify a plan for providing SNAP for households that are victims of a disaster and that such plan shall include, but not be limited to, procedures for informing the public about the disaster program and how to apply for its benefits. The plan should also give consideration to coordinating efforts with other Federal and private relief agencies, as well as local government officials.

Has the Department previously published rules for D–SNAP?

The Department published the interim rule in 1981, at 46 FR 8922–01 (January 27, 1981) (amended in 1991 and 2005), which established the Department's authority to approve temporary emergency standards of eligibility for disaster victims without regard to Section 4(c) of the Act or the procedures set forth in the Administrative Procedure Act (5 U.S.C. 553). Based on this authority, as disasters have occurred, the Department has approved the specific procedures to be used, depending on the circumstances of each particular disaster. The procedures in the interim rulemaking (that was never published as a final rule) for certifying disaster-affected households and issuing D–SNAP benefits initially served as a basis for D–SNAP guidance to States. FNS guidance has since evolved and has been updated as necessary based on experience and States' needs.

Would this proposed rule address the "Disaster Task Force" discussed in the Act?

The proposed rule does not address the D–SNAP task force. FNS employs staff at its national office and in its regional offices that work with State staff, and coordinate with other Federal agencies in preparing for disasters. FNS staff assists with D–SNAP operations as appropriate, including going on-site in many instances. While these staffs change over time in response to the need for disaster-related activity, they constitute the flexible type of task force contemplated by the Act. Thus, there is no need to regulate this provision of the Act.

What do the current interim regulations for D–SNAP say?

The interim regulations currently in effect state that:

- The Secretary shall, after consultation with the official empowered to exercise the authority provided for by the Stafford Act, establish temporary emergency standards of eligibility for the duration of the emergency for households who are victims of a disaster which disrupts commercial channels of food distribution, if such households are in need of temporary food assistance and if commercial channels of food distribution have again become available to meet the temporary food needs of such households.
- Such standards as are prescribed for individual emergencies may be promulgated without regard to section 4(c) of this Act or the procedures set forth in 5 U.S.C. 553.
- In addition to establishing temporary emergency standards of eligibility, the Secretary shall provide for emergency allotments to eligible households to replace food destroyed in a disaster. Such emergency allotments would be equal to the value of the food actually lost in such disaster but not greater than the applicable maximum monthly allotment for the household size.
- The Secretary may also approve alternate methods for issuing food stamp benefits during a disaster when reliance on Electronic Benefits Transfer (EBT) systems is impracticable.

What has the Department learned using this authority?

The Department has learned several lessons over the years. First, each disaster situation is different and it is important to provide States flexibility in requesting a D–SNAP that will meet the needs of the disaster victims and is compatible with the State's plans and administration. Second, disaster planning and preparation are critical to a timely and well coordinated response to different disaster situations. Third, State monitoring and reporting on program operations and integrity must be integrated into the planning and implementation of any D–SNAP.

What aspects of the D–SNAP does the proposed rule address?

This proposed rule primarily addresses several aspects of the D–SNAP, including:

- The development of a Disaster Plan
- Circumstances necessary for approval of a D–SNAP
- Required content of the State request to FNS for a D–SNAP
- The basic eligibility and benefit policy for participation in D–SNAP
- The application processing requirements for D–SNAP
- Policy regarding currently certified SNAP participants residing in disaster areas
- Monitoring State D–SNAP operations
- State Reporting on D–SNAP (both during and at the conclusion of disaster operations)

Does this proposed rule establish detailed operating and policy requirements for all D–SNAP operations?

This proposed rule is intended to provide as much flexibility as possible in the design of each D–SNAP operation while establishing consistent rules for requesting, monitoring and reporting on the D–SNAP. The reason for this is the varied and unpredictable nature of each disaster. While there are similarities among disasters, each set of circumstances is different enough that any attempt to limit State and FNS flexibility could cause delays in Federal and State response time in providing benefits to the victims of disasters. Thus, regulations that inherently seek to standardize policy and procedures, regardless of specific circumstances, can become problematic when the circumstances call for flexibility. In this proposal, the Department provides a basic framework for D–SNAP that sets clear expectations for State and local administrators while still allowing as much flexibility as possible. Furthermore, the Department is attempting to provide responsible fiscal controls of the disaster benefits while ensuring that benefits are provided to eligible applicants during disasters.

Does FNS provide additional direction or guidance regarding D–SNAP?

Yes, FNS provides detailed guidance which can be found on the FNS Web site at *http://www.fns.usda.gov/disasters/response/D-SNAP_Handbook/D-SNAP_handbook.pdf.* This guidance is based upon lessons learned by FNS and States' best practices in several types of disasters. It is designed to assist States in all aspects of the D–SNAP. Adherence to this guidance can improve preparedness, expedite approval of requests and reduce the potential for waste and fraud in D–SNAP operations.

When is it appropriate to request D–SNAP?

D–SNAP timing varies with the unique circumstances of each disaster, but begins after there has been a Presidentially-declared disaster for IA and commercial channels of food distribution have been restored so families are able to purchase and prepare food.

What is IA?

IA is financial or direct assistance to individuals and families whose property has been damaged or destroyed as a result of a Presidentially-declared disaster, and whose losses are not covered by insurance. The decision to designate an area as eligible for IA is made by FEMA. The IA is intended to help households with critical expenses that cannot be covered in other ways.

FNS proposes to approve the operation of D–SNAP under Stafford Act authority when affected areas have received a Presidential disaster declaration for IA because receipt of an individual assistance declaration is indicative of households' need for food assistance in the affected area. However, since D–SNAP is intended to meet households' immediate needs, States would be required to implement D–SNAP within a reasonable time period following the IA declaration. FNS is reluctant to approve requests for D–SNAP that are made after the immediate need for food assistance has passed.

How is D–SNAP funded?

FNS provides 100 percent of disaster benefits and 50 percent of State administrative costs.

What is a State's responsibilities in D–SNAP?

The Department proposes that the primary responsibility for providing emergency food assistance continue to rest with the States. State agencies would continue to design their own D–SNAP Plan, evaluate the need for a D–SNAP or another feeding program when a disaster strikes, submit a detailed request to FNS to operate a D–SNAP, effectively implement the D–SNAP, ensure program integrity in D–SNAP operations, submit daily reports, perform post-disaster reviews, and report their findings to FNS.

Basic D–SNAP Policies

How do D–SNAP non-financial eligibility criteria differ from SNAP?

Eligibility criteria vary depending upon the disaster, the demographics of the affected jurisdictions and States' D–SNAP requests. FNS has exercised its disaster authority to waive SNAP eligibility restrictions, streamline States' D–SNAP operations and ensure that families in the affected areas are served as efficiently as possible.

How is the allotment calculated in D–SNAP?

D–SNAP provides a full month's allotment to disaster affected households who may not normally qualify for or participate in SNAP. The allotment for a household is equal to the maximum monthly allotment for the household size provided under SNAP.

D–SNAP allotments are updated yearly and available on the FNS Web site. In order to serve disaster affected households already participating in SNAP and residing in areas approved to operate a D–SNAP, States may supplement the SNAP benefit up to the maximum allotment for the household size.

What is the D–SNAP "Application Period"?

The Department proposes that States may only accept applications for D–SNAP benefits from households not participating in SNAP and requests for supplements only from households currently certified in SNAP during the approved application period. FNS has generally approved application periods of 7 consecutive days (business days at the State's option), though States have the option to request more or fewer days in the D–SNAP request. FNS proposes to continue with this approach. The State should also inform FNS, as part of the D–SNAP request, whether applications will be accepted on Saturday and/or Sunday. If the State is accepting requests for supplements from households currently certified in SNAP over the phone and mailing the forms to the household, the required affidavit attesting to the loss of food purchased with SNAP benefits must requested during the application period.

What is a D–SNAP "Benefit Period"?

The Department proposes that the benefit period be a 30-day period approved by FNS for each D–SNAP. The benefit period is the period during which disaster-related expenses are to be counted; the start date is used to determine household composition and resources. Only income received, expenses incurred and resources that are accessible during the benefit period are considered in determining D–SNAP eligibility. The benefit period begins on the first date of the disaster generally referred to as the "Incident Period" identified in the Presidential Disaster Declaration.

Can the Application and Benefit Periods be modified?

The Department proposes that any modifications to a D–SNAP be approved by FNS in writing. For example, if a State agency determines that the initial benefit period requested is not appropriate, it may request a modification of the benefit period start/end dates. This could, for example, accommodate disaster related expenses incurred in preparation for the disaster. However, once the application period has commenced the benefit period could not be changed. Doing so would introduce unnecessary complexity and potential inequity into the D–SNAP.

If demand for D–SNAP benefits increases or remains high during the initially approved application period, FNS may consider a State's request for an extension of the application period. States requesting an extension should address the ongoing demand for assistance and any program integrity concerns in their request.

What are the basic eligibility criteria for D–SNAP?

To be eligible for D–SNAP, the Department proposes that an applicant household must first meet basic criteria, including: (1) Residency; (2) Household Composition; (3) Adverse effects due to the disaster; and (4) Income requirements.

How is residency determined?

Under this proposed rule, the household must have lived in the disaster area at the time of the disaster. However, States may also choose to extend eligibility to those who worked in the disaster area at the time of the disaster. When submitting their D–SNAP requests, States should specify if they will serve households that (a) lived in the disaster area, or (b) lived or worked in the disaster area.

How is household composition established?

The Department proposes that D–SNAP household composition be established based upon persons who live, purchase food, and prepare meals together on the date of the first day of the disaster benefit period, which will be considered to be the earliest date that households are in need. This rulemaking proposes that the benefit period begin on the date of the disaster or the date of any mandatory evacuation preceding the disaster.

What is an adverse effect?

The Department proposes that disaster-related adverse effects include three categories:

○ Loss or inaccessibility of income involving a reduction or termination of income, or a significant delay in receipt of income.

○ Inaccessibility of liquid resources, including situations in which the household is unable to access cash resources for a portion of the disaster benefit period.

○ Disaster related expenses that the household has incurred during the disaster benefit period that result from the effects of the disaster.

The FNS Disaster SNAP Guidance provides specific expenses that shall be considered disaster related, and States can propose other reasonable expenses in their disaster request.

How is household income dealt with for D–SNAP?

The Department proposes that the income of households that meet the residency, household composition and adverse effect criteria be measured against the D–SNAP gross income limit

(DGIL) in order to determine eligibility. The DGIL is explained below.

Unlike SNAP, which includes separate tests for income and resources, the Department proposes that D–SNAP would group income and resources together under one test. This is the method that is already being used in D–SNAP. To determine a household's D–SNAP income:

- Add all income received or expected to be received during the benefit period to accessible liquid resources (liquid resources include cash on hand, and funds in accessible checking and saving accounts on the first day of the benefit period);
- Subtract the value of unreimbursed disaster related expenses incurred during the disaster benefit period from the income/liquid resource amount (any reimbursements received or anticipated to be received by the household during the benefit period, including insurance and FEMA payments would reduce the allowable disaster-related expense amount); and
- Compare the result compared to the DGIL and if it is less than or equal to the DGIL, the household would be eligible for D–SNAP benefits.

What is the Department proposing to include as D–SNAP income?

The Department proposes that D–SNAP income would be the net (take-home) pay of all household members during the benefit period, including:

- Wages a household actually receives after taxes and all other payroll withholding (including contributions to 401(k) or other inaccessible accounts, automatic payments to creditors, etc.);
- Public assistance payments or other unearned income; and
- Net self-employment income.

As determined by the State agency, income that has been delayed for a substantial portion of the benefit period due to the disaster would be considered inaccessible.

For example, household X consists of four people who are not currently participating in SNAP. Their household was impacted by the disaster and they apply for D–SNAP. One individual is employed and receives monthly take-home pay of $1200, after payroll taxes and health insurance premium are taken out. The other individual receives $850 in TANF benefits each month. The household's total income for D–SNAP purposes is $1200 + $850 = $2050.

What is the Department proposing to exclude as D–SNAP resources?

The Department proposes that the following be deemed as not accessible liquid resources:

- Retirement accounts;
- Disaster insurance payments;
- Disaster assistance received or expected to be received during the benefit period; and
- Payments from Federal, state or county/local government agencies or disaster assistance organizations (including disaster-related Unemployment Compensation).

Inaccessible liquid resources would also include otherwise liquid resources that are temporarily inaccessible (for instance, because a bank with a household's certificate of deposit is closed due to the disaster) during the benefit period. In the Department's experience, this is an infrequent occurrence, as households can usually access their resources via online banking or ATMs even if bank branches are closed in the affected area. For example, on the day the disaster struck, household X had $50 in cash, and $250 in its checking account, with an additional $300 in a savings account. The funds in these accounts are accessible. The household has applied for FEMA assistance for the property damage it incurred. The household's total accessible liquid resources are $50 + $250 + $300 = $600, since the FEMA assistance will not be received before the benefit period ends. Their household's total accessible liquid resources are $50 + $250 + $300 = $600.

How is the DGIL calculated?

The Department proposes to calculate each year's disaster gross income limit by adding together the SNAP maximum monthly net income limit, the SNAP maximum standard income deduction amount, and the SNAP maximum capped shelter expense deduction for each household size. Together, these amounts establish a simplified process to determine if households are in need of assistance that is grounded in the SNAP income methodology and standards for determining eligibility. For household X in the above examples, the total D–SNAP "income" of $2650 ($2050 + $600), would be compared to the DGIL for a household of four to determine eligibility for D–SNAP.

How is the requirement that households purchase food applied?

The Department proposes that, to be eligible, households must either plan on purchasing food during the disaster benefit period, or have already purchased food during the benefit period. This would clearly apply to most households, other than with very large disasters where households may remain in shelters and be served through congregate feeding throughout the benefit period.

What are disaster-related expenses?

These are expenses that the household has incurred during the disaster benefit period due to the disaster. Eligible expenses would include the following, plus any other reasonable disaster-related expenses determined by the State agency:

- Home or business repairs
- Temporary shelter expenses
- Evacuation expenses
- Home/business property protection
- Medical expenses due to personal injury
- Disaster-related funeral expenses
- Expenses related to replacing necessary personal and household items, such as clothing, appliances, tools, and educational materials
- Fuel for primary heating source
- Clean-up items expense
- Disaster-damaged vehicle expenses
- Storage expenses
- Food lost in the disaster

Are all disaster-related expenses deductible?

In the past, all of the above expenses would be deductible if they have been or are anticipated be paid during the benefit period unless the household receives or anticipates receiving a reimbursement for these expenses during the benefit period, in which case only any remaining obligation expense is deductible. The Department's practice to date has been only to allow a deduction for expenses which are paid during the benefit period. Consequently, bills paid by credit card or other payments over time have not been allowed as deductions. The Department is now proposing to allow deductions for expenses that are incurred during the benefit period even if those expenses will be paid after the benefit period. The Department believes that this policy would be more equitable since households that incur similar disaster related expenses should not be treated differently simply because they pay using a credit card instead of cash or a check. The Department is interested in receiving comments on this proposed change.

What options do States have in determining deductions?

In conjunction with the options discussed below, the Department proposes that States may also choose to consider households that have experienced food loss as their only disaster-related expense to be eligible for the D–SNAP. The State would use available information such as power outage maps showing affected homes or zip codes to determine if allowing eligibility based upon food-loss alone is appropriate. Households reporting excessively large amounts of food loss, or any other questionable information, would be referred to fraud investigators or senior staff for further review.

This proposed rule would provide States the following two options in determining if households have disaster-related expenses and the amount of the expense to use in determining D–SNAP income. The option selected would be identified in the State's D–SNAP request.

- Use of the disaster-related expenses identified above and in the FNS Disaster SNAP Guidance. Under this option, states may choose to have food-loss only or food loss plus one additional disaster related expense in order to be eligible.
- Use of a Disaster Standard Expense Deduction (DSED). For households with $100 or more in deductible disaster-related expenses (including food loss), the DSED would be added to the disaster gross income limit and households whose take-home pay plus available liquid resources is less than or equal to this amount (DSED+DISASTER GROSS INCOME LIMIT) would qualify for D–SNAP benefits. Because the DSED is designed to capture food loss along with other disaster-related expenses, such as loss of income and damage to or destruction of property, as noted earlier, it could not be applied to cases in which food loss is the only disaster-related expense.

The DSED that has been used by several States is based upon information gathered from actual disaster-related expenses reported in a prior D–SNAP. As proposed in this rulemaking, only households with actual, unreimbursed disaster-related expenses equal to or greater than $100 would qualify for the DSED. Households with deductible disaster-related expenses that fall below the $100 threshold would have their eligibility determined using their actual expenses. If a household has disaster expenses which exceed the DSED for its size, the State may, at its option, use actual expenses to determine eligibility.

How is food loss in a disaster addressed in the proposed rule?

The Department proposes that the loss of food due to the disaster be considered a disaster-related expense and that including "food loss alone" as a criterion for eligibility be optional and be addressed in the D–SNAP request to FNS. It is important to note that households currently certified in SNAP can always request the replacement of lost food that was purchased with their SNAP benefits under standard SNAP rules. Food lost or spoiled due to the disaster or extended power outage is always considered a disaster expense.

What verification is required in a D–SNAP?

The Department proposes that verification rules be eased (relative to SNAP) to reduce administrative burdens and to reflect the reality that due to the nature of a disaster, households and eligibility workers may not have access to usual verification sources. Proposed verification requirements for D–SNAP in the proposed rule are three-tiered:

- Identity must be verified;
- Verification of residency and household composition must be attempted in all cases, and must be pursued if questionable; and
- Loss/inaccessibility of income or liquid resources and food loss must be verified if questionable.

Such verification shall be performed in accordance with the requirements at 7 CFR 273.2(f).

What requirements are proposed regarding duplicate participation

The Department proposes that States check for duplicate information up front or accept applications and inform applicants that eligibility is contingent upon a subsequent duplicate check. States would be required to screen all household members for duplicate participation in:

- D–SNAP and SNAP
- D–SNAP and disaster commodity food assistance
- Multiple D–SNAPs with overlapping benefit periods
- Approved D–SNAP and denied D–SNAP applicants (to identify attempted duplicate participation)

Disaster Plan

What does the rule propose requiring in States' disaster plans?

The Department proposes in § 280.1(b) that the State Disaster Plan must include the following information:

- Agencies and Responsibilities. This would identify State and Federal government agencies with responsibilities for disaster assistance, including a description of responsibilities for each agency.
- Points of Contact. This would provide names, positions, and phone numbers of county/local, State and Federal government officials, and their back-ups, who are key contact persons during a disaster (including the State agency disaster coordinator).
- Community Partners and Roles. This would identify private disaster relief agencies within the State, such as the Red Cross, Salvation Army, or community groups, and a description of their roles in D–SNAP implementation.
- Staffing and Resources. This would identify staffing and related resources available to assist in a disaster, and how they will be mobilized to target disaster areas in need. It would also explain how the State/counties will manage the increased administrative burden associated with running a D–SNAP and SNAP operations simultaneously.
- Application System. This would describe application systems to be used for D–SNAP household management, including any workarounds to the SNAP system, considerations associated with running SNAP and D–SNAP operations concurrently, compliance with D–SNAP reporting requirements, etc.
- Issuance System. This would describe benefit issuance systems to be used for D–SNAP household management.
- EBT Card Stock. This would identify EBT card stock available, type of cards to be used, steps and timeline for ordering additional cards, and any special procedures or resources that will be needed to meet SNAP and D–SNAP issuance timeframes.
- Application Sites. This would describe site selection procedures, including potential application/issuance sites for disasters that vary in size and scope, and any agreements in place with those locations. If D–SNAP will operate out of local offices, it would explain how application sites will handle running D–SNAP and SNAP concurrently.
- Data. This would identify general demographic data that can help the agency tailor its response to a disaster. It would identify resources and contact information for disaster impact data, including preliminary data assessments, flood maps, or electrical outage data.
- Public Information and Outreach. This would describe public information strategy to ensure that timely, accurate information reaches eligible households. It would outline roles, expectations, and responsibilities of any SNAP outreach partners included in the State Outreach Plan that will assist with D–SNAP.
- Retailer Communication. This would describe procedures to notify retailers of new waivers (see discussion of the potential for hot foods below) and new D–SNAP households.
- Procedures to Reduce Applicant Hardship. This would outline steps the State will take to reduce hardship for D–SNAP applicants and SNAP caseload, including provisions for security, human needs, language services, elderly/disabled, etc.

- Certification Process. This would describe the specifics of the certification process, including potential application sites, staffing, separation of eligibility and issuance, and how application sites will manage large crowds. If online applications are to be used by workers or households, the plan would describe that process and back-up systems in place if the online system is not available.
- Use of a DSED and the income limits.
- Reasonable Accommodations for Individuals with Disabilities. This would describe what special accommodations will be made for individuals with disabilities at the application and issuance sites. This section may also include special accommodations to provide program access to individuals with disabilities beyond those required at application and issuance sites, such as transportation services or home visits, as determined by the State agency on a case by case basis, but without imposing an undue burden on the State agency.
- Household Materials. This would include sample household application and household notices in various languages.
- Issuance Process. This would describe how benefits will be made available within 72 hours of D–SNAP application and how to ensure continuation of SNAP certification, issuance, and other actions concurrently. It would indicate how the State will monitor stock levels and ensure sufficient EBT card stock. It would describe EBT card on-site or mail issuance procedures and reconciliation, as well as security procedures, including how D–SNAP benefits will be tracked separately from SNAP benefit issuance. Plans would need to adhere to FNS reconciliation guidelines so benefits posted to accounts can be compared to benefits issued by the State eligibility system.
- Security and Fraud Prevention Plan. This would describe how the State will ensure security and mitigate the risk of fraud, including a specific plan for handling applications submitted by State agency employees, procedures for handling questionable applications, process for checking all household members for duplicate participation, and any onsite security.
- Disaster Reporting and Post-Disaster Review Report. This would describe procedures to ensure that required federal reporting and post-disaster review report will be complete and timely. This would include daily reporting.

Disaster plans should also address any circumstances unique to the State which may affect D–SNAP operations, including: Coordination of resources among County-level administrations; serving isolated populations, the development of "work-arounds" to allow SNAP systems to accommodate D–SNAP operations; and, contingency plans for local offices located in flood plains or otherwise subject to closure.

Conforming amendments are proposed in 7 CFR 272.2(a), 272.2(d), and 272.2(e) to acknowledge the Disaster component of the State agency's overall State plan.

How often should the D–SNAP Plan be updated?

To ensure that necessary advance preparations are current, the Department proposes in § 280.1(b) of this rulemaking that State agencies be required to review their existing Disaster Plan on at least an annual basis and submit a revision, if a substantive change is being made, or a notice of no substantive change, for FNS approval by the 15th of August each year or another negotiated due date approved by FNS. As specified in § 280.8(f), State agencies would be required to amend the plan if deficiencies are found in a D–SNAP post-disaster review. If plans are not changed from the prior submissions, States would be able to submit letters to this affect rather that a complete plan.

What training is required related to the D–SNAP plan?

The Department proposes that, at a minimum, States be required to provide D–SNAP training to management in each SNAP local office and call center. While FNS encourages that training be as complete and inclusive as practical, at least one manager (perhaps a D–SNAP coordinator) from each SNAP office must be included in whatever training the State deems appropriate.

What State System requirements are there related to D–SNAP preparations?

While there is a variety of programming that could be in place to be ready in preparation for a disaster and improve operational efficiency, each State is expected to make such choices based upon their administrative needs and system capabilities. The exception to this general expectation is that the Department proposes to require that every State have the ability to check for duplicate participation for all household members, as well as conduct reconciliation of D–SNAP benefits and generate the reports required by this rule. This includes being able to track disaster benefits separately from SNAP benefit issuance. States would also need to have a method in place to allow for tracking of multiple D–SNAPs simultaneously should they be struck by two disasters within a short timeframe. States also must adhere to FNS reconciliation requirements so that they can compare benefits posted to accounts to benefits issued by the State eligibility system.

Requesting D–SNAP

What is required in the D–SNAP request?

The Department proposes that D–SNAP requests be submitted with a signed cover memorandum from the State that includes a thorough explanation of the components listed below. Well-documented requests can be considered and approved more quickly—clearly a priority in a disaster situation. It is proposed that each D–SNAP request include:

- A description of the disaster—what happened, dates it occurred, the affected area.
- The geographic area and explanation of any differences between the area included in the presidential declaration and the requested area in which to operate the D–SNAP.
- The start and end dates of the application period. If it will be staggered, give dates for each county/area. Note if application sites will be open over the weekend or for extended hours.
- The start and end dates of the 30-day benefit period. The start of the benefit period should generally match the first day of the "incident period" on the disaster declaration. If not, the State should explain the reason for the difference.
- Whether a DSED is being used and how it is structured.
- Whether only households that lived in the disaster area will be eligible for D–SNAP or if households that worked in the disaster area will also be eligible.
- Whether "food loss alone" will be a criterion for eligibility.
- Whether supplements will be automatic or individual (by affidavit of disaster) for currently participating SNAP households. If automatic, the request would need to describe who is eligible and include supporting data. Supporting data may include but is not limited to an estimate of the value of issuances for automatic supplements. If individual, the request would need to include information on the process for requesting supplements—by phone/mail affidavit, electronically, or in person at a local office/D–SNAP application site.
- The estimated total number of people, homes, businesses, etc.,

impacted by the disaster, as well as estimates of anticipated D–SNAP applicants and number of currently certified SNAP households expected to be served, along with an explanation of how the estimates were derived.

- A description of issuance procedures, the number of EBT cards on hand, and plans for requesting, receiving, and distributing additional cards as needed. The request would need to indicate whether D–SNAP cards can be replaced if lost or stolen.
- A description of the plans for publicity, application sites, and security/crowd control.
- Plans for utilizing staff from other program areas, counties, or States, as appropriate. The request would need to indicate number of staff available and how staff/supervisors will be distributed among the application sites.
- A description of application sites, security/crowd control, and procedures to ensure program access and reasonable accommodation for persons with disabilities.
- A description of when and how program information will be disseminated to the public. This would include a list of partner organizations involved and describe the responsibilities of each, including role of volunteers, if applicable. It is important that sufficient time be allowed to notify the public prior to the start of the program. Examples of partner activities include providing D–SNAP information on behalf of the State or providing onsite application assistance.
- A description of the fraud prevention strategies and security measures in place.
- A description of the recipient claim procedures and thresholds to be followed if they differ from regulations at § 273.18 or the State's FNS-approved procedures for handling recipient claims in SNAP.
- A description of the procedures that will be used for identifying and handling applications by State agency/State employees.
- Draft press releases, sample application, preliminary damage assessments, and map of disaster area.

In addition to these required items, other supporting documentation may be included.

When should requests for D–SNAP be submitted?

Since the purpose of D–SNAP is to meet households' immediate needs, the request should be submitted to allow for implementation of D–SNAP within a reasonable amount of time following the IA declaration. In addition, it should be submitted to FNS at least several days prior to the planned implementation date to allow time for FNS review and approval. Most importantly, the State should allow sufficient time to effectively publicize the availability of D–SNAP for the affected population prior to implementation. The Department is interested in receiving comments on whether there is a need to establish a standard time frame for submission of requests for D–SNAP relative to the projected implementation date.

What changes can be made to the D–SNAP after implementation?

Sometimes, States' approved requests for D–SNAP need modification. As with the initial submission, the Department is proposing that States must submit written, signed requests for changes to an approved D–SNAP. These requests, and their corresponding approvals, would generally be approved more quickly than the initial waiver, since much of the information about the disaster is already known. The three most likely types of changes to the D–SNAP are listed below, along with an explanation of each.

Expansion—After initial approval, a State may want to expand operations because an additional county is in need of the program. While the application period in the expanded area may differ from what was originally approved, the benefit period will generally remain the same. In such cases, the State should submit to FNS a request for expansion, detailing the impact of the disaster in the new area, the application period, and the anticipated number of applicants and currently certified SNAP households that will be served. If the benefit period will change, for example, because flooding due to the same storms struck another County at a later date, the new benefit period's dates and justification should also be included.

Extension—In some cases, States may find that their initial application period is not sufficient to serve all eligible households, and so they may wish to request that the application period be extended. Requests to extend the D–SNAP application period must be submitted with sufficient time for FNS review and approval prior to the end of the initial application period and must be accompanied with justification of the need for additional time. Once the application period has ended and operations have closed, further extensions would not be permitted.

Modification—A request to change an aspect of the D–SNAP other than those mentioned above is known as a modification. Most modifications, including any that would affect applicant eligibility, can only be made prior to the start of the application period to ensure that the eligibility criteria are applied equitably to all applicants. Occasionally, modifications may be made after D–SNAP operations have begun, such as when a State that was originally approved for individual supplements decides to issue automatic supplements in a certain area. Because of the limited window of time in which most modifications can be requested, FNS encourages State agencies to carefully consider their program options prior to submitting the initial request.

Are there other waivers that must be requested separate from the D–SNAP request?

There are operational and policy issues that, while are related to the disaster situation, are not included under the authority of the D–SNAP and so are not addressed in this proposed rule. The one exception is the extension of the timeframe to report a loss and request replacement of food purchased with SNAP benefits as addressed below. While this proposed rule only addresses the waiver for Timely Reporting of Food Loss, three additional waivers are also discussed, for informational purposes only, because they are the most frequently requested and approved relative to D–SNAP operations.

Timely Household Reporting of Food Loss—SNAP regulations at § 274.6 require that replacement issuances be provided to current SNAP recipients only if a household reports a loss of food purchased with SNAP benefits to the State within 10 days of the date the food is destroyed in a household misfortune. This waiver has allowed the State agency to extend the amount of time households have to report the loss of food purchased with SNAP benefits beyond 10 days. The Department proposes to change the reporting timeframe for the loss of food purchased with SNAP benefits from 10 days to 30 days when the President issues a major disaster declaration for IA. In all other cases, the 10-day timeframe would remain intact.

Automatic/Mass Replacements—Per SNAP regulations at § 274.6, replacement benefits are available (by affidavit) to SNAP households anytime they experience an adverse effect causing them to lose food purchased with their benefits. This waiver allows the automatic replacement of a certain percentage of a household's benefit (depending on the time of the month, the State's benefits issuance cycle, and the type of disaster) for all participating households within the disaster area, without the need to submit individual requests. This waiver may be granted without a D–SNAP approval or IA designation. This waiver does not remove the responsibility of local offices to process individual affidavits before or after the waiver implementation as required by § 274.6(a).

Hot Foods—A waiver of the hot foods exclusion in the Act allows SNAP households to purchase hot, prepared foods at authorized retailers with their EBT cards. FNS has the authority to grant this waiver provided that an IA declaration has been issued. The coverage of this waiver may extend to areas beyond those that received D–SNAP approval if households that lived in the disaster area have been displaced or temporarily relocated to other parts of the State.

Expunging D–SNAP benefits—State agencies may request to use a shorter timeframe (typically 90 days) for expunging benefits for D–SNAP-only households. Following the implementation of the Food and Nutrition Act of 2008, Pub. L. 110–246, this waiver requires approval from FNS. State agencies that wish to implement this waiver must submit it along with their D–SNAP requests. Any State operating under this waiver must inform D–SNAP-only households of the timeframe for expunging benefits. This waiver may only be used when the State has received approval to operate a D–SNAP and an IA declaration has been issued. A prerequisite for this waiver is the ability of the State automated system to identify the disaster cases and benefits separately from SNAP cases (this is required for FNS reporting as well).

Issuance and Reconciliation

What are the Issuance requirements in D–SNAP?

The Department proposes to require that each State be prepared to issue D–SNAP benefits through its EBT system during an emergency. As noted earlier, EBT issuance is also proposed as a required component of State Disaster Plans. As such, a State's D–SNAP issuance plan should incorporate procedures for:

- Ensuring that approved households have benefits available, including EBT cards, and Personal Identification Numbers (PINs), and that their benefits are available no more than 72 hours from when the application was filed, unless there is questionable information on the application that requires verification. In these latter situations the State may extend the 72-hour time frame for making benefits available to no more than a total of seven days from the date of application.
- Accessing sufficient card stock to operate a D–SNAP.
- Replacing households EBT cards that are lost in a disaster as soon as possible but within the card replacement timeframes required at 7 CFR 274.6(b). If the normal EBT replacement process is to mail the replacement card to the household's home, and the disaster response requires card delivery to a disaster issuance site or alternative address in a non-disaster area, the State must be able to override the EBT system.

What does the rule require regarding replacing EBT Cards for currently certified SNAP households?

The Department proposes that when SNAP households lose their EBT cards in a disaster, the EBT disaster system design have procedures for providing currently certified SNAP cases with replacement cards as soon as possible, but always within the card replacement timeframes required at 7 CFR 274.6(b). Specifically, current SNAP regulations require State agencies to make replacement EBT cards available for pick up, or to place the card in the mail, within two business days following notice by the household to the State agency that the card has been lost, stolen or damaged. However, under a D–SNAP situation, the Department proposes to require State agencies to make reasonable efforts to replace EBT cards sooner if possible; the Department is not requiring a specific or more stringent timeframe for making card replacements under D–SNAP situations in order to provide States and their EBT processors some flexibility in unpredictable situations. However, the Department also wishes to ensure that clients receive their cards as soon as possible under circumstances in which the household may have not only lost their card, but all their food as well. The Department welcomes comments on whether or not a more specific and stricter card replacement timeframe should be implemented for D–SNAP situations.

What are the D–SNAP reconciliation requirements?

The Department is proposing that the State be required to develop a system for reconciling both cards and benefits. Cards shipped from a central location would be required to be tracked until distributed locally to households. Each issuance site would be required to maintain a beginning and ending inventory and track new cards received, total cards available, and cards issued. If the State assigns PINs, they must also account for PIN mailers or envelopes to ensure adequate security, except when the PIN is formulated by some other means, such as from the Primary Account Number (which is a number on the EBT card and encoded onto the card to identify the State and EBT account holder.) The State would also be required to:

- Reconcile the number of cards set-up with EBT accounts and the number of cards issued and then research and explain any discrepancies;
- Track D–SNAP benefits separately from SNAP benefit issuance; and
- Adhere to FNS reconciliation guidelines so that they can compare benefits posted to accounts with benefits issued by the State eligibility system.

Currently Certified SNAP Households

How does the SNAP work during a disaster?

The Department recognizes that SNAP households will often need replacement benefits or supplements. As noted earlier in the discussion of the D–SNAP request, currently certified SNAP households are not eligible for D–SNAP, but those affected by the disaster are generally eligible for a supplemental issuance.

What are supplements?

Supplements are additional benefits issued to SNAP households affected by the disaster in amounts that bring the households' benefit level up to the maximum allotment for their household size. Supplemental benefits provide parity between new D–SNAP households and SNAP households. By virtue of their participation in SNAP, the food needs of SNAP households are already known. The request to issue individual or automatic supplements (see below), and the supporting justification, must be included in the State's D–SNAP request. By addressing the needs for SNAP households immediately, and prior to the start of D–SNAP operations, overcrowding of SNAP participants seeking service at D–SNAP locations can be minimized.

What is the difference between individual and automatic supplements?

Under this proposed rule, the State agency must decide if it is most appropriate to issue supplemental benefits on an individual basis, via the filing of an affidavit by the household, or automatically, to all currently certified SNAP households in a designated area. To obtain an individual supplement, households are required to complete an affidavit of disaster impact. For this reason, individual supplements work best in areas where there is a small-scale disaster and applicant volume is not anticipated being very high. For individual supplements to be effective, the State agency must have the capacity to handle the individual requests for supplements, and issue the supplemental benefits, while it is also taking D–SNAP applications.

Automatic supplements are additional benefits issued to all currently certified SNAP households in a defined geographic area and are appropriate when the majority of that area is impacted by a disaster. They are intended to help SNAP households deal with the impact of the disaster and generally work best when the State agency is able to clearly identify areas in which households share the adverse effects of the disaster, such as the loss of electrical power. Automatic issuance can help the State agency quickly and efficiently meet the needs of SNAP households, while freeing up staff and resources to direct toward the population of new D–SNAP applicants.

The Department is proposing that States include their desire to issue automatic supplements in their D–SNAP requests and demonstrate their ability to effectively target the benefits to geographic areas that were heavily impacted by the disaster. Any SNAP households not designated to receive automatic supplements, that were living in the area approved to operate D–SNAP and experienced disaster losses, may still request supplemental benefits via an affidavit of disaster. As with replacements benefits (discussed below), requests for automatic supplements must be accompanied by supporting data which indicates that a majority of the population in a given area has suffered an adverse effect as a result of the disaster. States should work closely with FNS to determine how to best find, use and evaluate available information in a post-disaster situation. This can include information from power companies, flood maps, or FEMA assessments.

Can already certified SNAP households obtain replacement benefits?

Replacement benefits are always available on an individual basis to SNAP households that lose food purchased with their benefits in a household misfortune. However, replacement issuances shall be provided to current SNAP recipients only if a household reports a loss of food purchased with SNAP benefits orally or in writing to the State within 10 days of the date the food is destroyed in a household misfortune. The Department is proposing that the 10-day timeframe to report a loss of food purchased with SNAP benefits be extended to 30 days when there is a major disaster declared under 7 CFR part 280. Reports will be considered timely if made to the State agency within 30 days of the date the food is destroyed. Household misfortunes such as mass power outages and flood and structural damage would qualify. In all other cases, the 10-day timeframe to report a loss of food would remain the same.

How do automatic/mass replacements work in D–SNAP?

As discussed earlier, the automatic/mass replacement requires a waiver that allows a State agency to replace a portion/percentage of currently certified households' monthly SNAP allotments in a disaster without the requirement that a household request a replacement individually, and travel to a local office to sign an affidavit of disaster. With this option/waiver, households would not have the added burden of signing paperwork and local offices would not have to process cases manually for each household needing a benefit replacement.

As with automatic supplements, approval of the mass replacement waiver typically requires a majority of the residences in the disaster area (county, zip code) to have lost power or be in another way affected by the disaster, resulting in the loss of food purchased with their benefits. Outages of four hours or more are typically considered. The replacement percentage is not fixed and generally depends on the time of the month in which the disaster took place as well as the State's issuance schedule. The extent and type of disaster (*e.g.,* flooding or power outages), perishables/non-perishables, and consumption, are also factors in determining the percentage of benefits to be replaced. In preparing requests for mass replacements, States need to assess the extent of the losses and provide justification for the percentage they request. Further, a mass replacement waiver does not remove the responsibility of local offices to process individual affidavits before or after the waiver implementation as required by 7 CFR 274.6(a).

Reporting

What does the proposed rule require in the daily reports?

The Department proposes that States operating a D–SNAP submit a daily report to FNS. Daily reports are used to monitor progress, troubleshoot problem areas, inform FNS policy officials, ensure that adequate funds are available in States' letters of credit and provide information to allow responses to inquiries from the media and other government agencies. The State agency would be required to begin submitting reports on the day following the first day of D–SNAP operations and continue submitting the reports on a daily basis until all applications are processed. FNS is proposing that all States utilize a daily reporting template provided by FNS in its D–SNAP guidance. Data would be submitted by county, as indicated in the template provided in FNS' D–SNAP guidance. The reports would contain:

1. Number of D–SNAP applications received
2. Number of new D–SNAP households approved
3. Number of new D–SNAP persons approved
4. Number of SNAP households receiving supplements
5. Number of people previously certified for SNAP approved for supplements
6. Number of new D–SNAP households denied
7. Number of SNAP households receiving replacement issuance
8. Value of new D–SNAP benefits approved
9. Value of SNAP supplements approved
10. Value of SNAP replacement issuance
11. Average benefit per new D–SNAP household
12. Average benefit per SNAP household
13. Any additional information the State believes FNS should be aware of

In addition to the quantitative data above, the inclusion of any qualitative information on challenges the State may have encountered with the daily reports will help keep State and Federal policymakers up to date on the situation on the ground.

What other D–SNAP reports does the proposed rule require?

In addition to the daily report, the Department proposes that the following be required from States with approved D–SNAPs:

Form FNS–292B, Report of Supplemental Nutrition Assistance Program Benefit Issuance for Disaster Relief—Within 45 days of the termination of a D–SNAP operation, the State agency would be required to submit its final disaster figures on form FNS–292B. All reports would be submitted electronically in the Food Programs Reporting System (FPRS).

Form FNS 292B would contain the following issuance data for D–SNAP operations:

- Number of new households issued D–SNAP benefits
- Total number of new persons issued D–SNAP benefits
- Number of households certified in SNAP that were issued supplements
- Total value of benefits issued to D–SNAP households and supplements issued to SNAP households.

The FNS–292B report would not include the value of any replacements issued. States would report the value of replacements on the FNS 388 Monthly Issuance Report.

Form FNS–388, Monthly Issuance Report—Form FNS–388 would reflect disaster issuance and participation figures, including replacement benefits. Replacement benefits should be reported for the month for which they are intended.

Form FNS–209, Status of Claims Against Households Report—In the remarks section of the FNS–209, State agencies would be required to indicate the number of D–SNAP claims established and collected. D–SNAP claims must be identified on backup documentation in accounting systems for form FNS–209.

- *Form FNS–46, Issuance Reconciliation Report*—States would be required to report D–SNAP issuance and returns in the Issuance and Returns section of form FNS–46. Forms FNS–46 and FNS–388 should reconcile with the reported net issuance.

Post-disaster Report—The Department is proposing that a post-disaster review report be required and that it be comprised of four parts: Comprehensive review, individual case reviews, problem analysis, and proposed improvements to the disaster plan. The comprehensive review should begin with an overview of the D–SNAP operation, including where and when it took place, how it was staffed, and the total number of applications approved and amount of benefits issued. The State should then describe the systems or methods employed, document any major issues (*i.e.* problems or challenges) encountered in any of the areas below, and discuss the interventions used to address those issues.

- Certification systems
- Fraud control
- Issuance
- Public information and outreach
- Program accessibility
- Security

The Department is proposing that individual case reviews include: A sample of approved D–SNAP cases; a sample of actions taken to deny applications for D–SNAP benefits; and a review of all approved applications for State agency employees. The review of approved cases would include: A case record review; an interview with the participant; verification of each element of eligibility for the State's D–SNAP program including identity, residency, income, household size and disaster related expenses; a determination of eligibility for disaster assistance; and an analysis of errors.

The Department proposes that States with 10,000 or more approved D–SNAP households (excluding State employees) select a sample of 400 approved cases for review. States with less than 10,000 but more than 300 approved D–SNAP households would select a sample of between 300 and 400 cases as shown below. States with 300 or fewer households would review all cases.

Approved D–SNAP households (N)	Minimum sample size (n)
10,000 and over	n = 400.
300 to 9,999	n = 300 + [0. 01031 (N − 300)].
Under 300	n = all cases.

The Department is proposing that a sample of 100 denied D–SNAP applications be reviewed to identify errors made in not providing benefits to eligible households. If there are fewer than 100 denied applications, all denied applications would be reviewed. Finally, the Department is proposing that States be required to review 100 percent of all State agency employee applications—approved and denied.

For all three types of case reviews, no cases would be dropped from the review results for any reason and the State would be required to report information gathered from all case reviews.

State agencies would be required to submit the post disaster report containing the results of the reviews, the problem analysis, and proposed improvements (that would be included in their next D–SNAP plan submission) within 6 months of the close of each D–SNAP operation.

Integrity

Along with the duplicate participation and verification discussed above, the Department proposes that additional safeguards should be built into D–SNAP operations.

What does the proposed rule require regarding fraud prevention?

An important aspect of fraud prevention is appropriate internal controls. To ensure that only eligible households receive benefits and that the amount of benefits issued is accurate, the Department is proposing that States operating a D–SNAP be required to:

- Input information for all household members into the eligibility determination system to prevent individuals from obtaining benefits as a member of more than one household.
- Input denied applications into the eligibility determination system each day, so that households that are denied and later reapply are detected and referred to fraud prevention staff. Note that such households may be eligible if their circumstances have changed.
- Check for duplicate participation by any individual applying for D–SNAP using onsite or offsite computer databases (or in disasters with very few applicants, hardcopy participant lists). Update computer database participant lists every day.
- Refer households without required verification or with inconsistent information to onsite investigators or highly-experienced staff for review.

What does the proposed rule require concerning employee fraud?

The Department recognizes that State agency employees may be legitimately eligible for D–SNAP benefits. States should take care to balance encouragement of eligible employees to apply for program benefits with the risk of employee fraud. The Department proposes that States be required to take these special measures to prevent employee fraud:

- Use separation of duties for certification and issuance.
- Include a question on the D–SNAP application asking if anyone in the household (or its authorized representative) is employed by the State, State SNAP agency, or County, if applicable.
- Utilize supervisors or investigators to conduct employee certification interviews.
- Audit all State agency employee applications and publicize that policy.

The proposed rule would require the State to review all applications from its employees and to communicate that to employees up front.

Are D–SNAP cases subject to quality control (QC) reviews?

Since the rules governing the determination of D–SNAP benefits differ significantly from the SNAP, D–SNAP cases are not subject to QC review and are not included when determining SNAP timeliness and payment accuracy rates. This is specified in 7CFR 275.11(f)(1). This is why the Department is proposing that States be required to conduct a comprehensive review of general program performance and reviews of individual cases.

What are the D–SNAP recipient claims collection requirements?

The Department is proposing that if a household receives D–SNAP benefits to which it was not entitled, the State agency must establish a claim against the household consistent with the claims collection requirements of SNAP regulations. Claims must be established as soon as possible after the close of the disaster operation. States may also either follow their FNS-approved procedures and thresholds for establishing claims in SNAP for claims arising from D–SNAP, or include alternate procedures or thresholds in their D–SNAP request.

If a claim is established against a household for an overpayment of SNAP benefits, the Department proposes that this amount may not be collected from the D–SNAP allotment. However, claims based upon D–SNAP over-issuances can be collected through a repayment agreement or through offsets against SNAP issuances.

D–SNAP Close Out

What happens after D–SNAP operations end?

The Department proposes that close out of D–SNAP Operations includes the following:

- Close out the D–SNAP application/ issuance sites;
- Transition eligible cases to SNAP;
- Submit issuance reporting and reconciliation;
- Pursue fair hearings, claims and restored benefits; and
- Submit post-disaster report.

What are the fair hearings requirements in a D–SNAP?

The proposed rule would require that:

- Any household who applied for D–SNAP benefits and was denied benefits may request a fair hearing;
- A household which has requested a fair hearing is entitled to an immediate onsite supervisory review;
- Households not satisfied with the outcome of this review retain the right to request a fair hearing through the normal process; and
- The number of fair hearings is reported on form FNS–366B, Program Activity Statement.

Are households entitled to restored benefits in D–SNAP?

SNAP regulations require State agencies to issue restored benefits to households when benefits were lost due to an agency error and when a denial of benefits is subsequently reversed. The Department proposes that this requirement also apply to D–SNAP benefits; State agencies should follow their normal procedures for issuance in such cases. The State's eligibility system must clearly indicate that an issuance was a restored D–SNAP benefit.

Executive Order 12866 and Executive Order 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

This proposed rule has been designated a not significant regulatory action. Accordingly, the rule has not been reviewed by the Office of Management and Budget.

Regulatory Impact Analysis

This proposed rule has been designated as not significant by OMB, therefore, no Regulatory Impact Analysis is required.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601–612) requires Agencies to analyze the impact of rulemaking on small entities and consider alternatives that would minimize any significant impacts on small entities. Pursuant to that review, FNS Administrator, Audrey Rowe, has certified that this proposed rule would not have a significant impact on small entities. State agencies that administer SNAP will be affected to the extent they choose to implement major changes in program operations. State agencies will also be affected to the extent they perform ME reviews of large, medium and small project areas.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local and tribal governments and the private sector. Under section 202 of the UMRA, the Department generally must prepare a written statement, including a cost benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures by State, local or tribal governments, in the aggregate, or the private sector, of $146 million or more (when adjusted for 2015 inflation; GDP deflator source: Table 1.1.9 at *http://www.bea.gov/iTable)* in any one year. When such a statement is needed for a rule, Section 205 of the UMRA generally requires the Department to identify and consider a reasonable number of regulatory alternatives and adopt the most cost effective or least burdensome alternative that achieves the objectives of the rule.

This rule does not contain Federal mandates (under the regulatory provisions of Title II of the UMRA) for State, local and Tribal governments or the private sector of $146 million or more in any one year. Thus, the rule is not subject to the requirements of sections 202 and 205 of the UMRA.

Executive Order 12372

SNAP is listed in the Catalog of Federal Domestic Assistance under No. 10.551. For the reasons set forth in the final rule in 7 CFR part 3015, subpart V and related notice (48 FR 29115, June 24, 1983), this Program is excluded from the scope of Executive Order 12372, which requires intergovernmental consultation with State and local officials.

Federalism Impact Statement

Executive Order 13132 requires Federal agencies to consider the impact of their regulatory actions on State and local governments. Where such actions have federalism implications, agencies are directed to provide a statement for inclusion in the preamble to the regulations describing the agency's considerations in terms of the three categories called for under section (6)(b)(2)(B) of Executive Order 13132. FNS has considered the impact of this rule on State and local governments and has determined that this rule does not have federalism implications. This proposed rule does not impose substantial or direct compliance costs on State and local governments. Therefore, under Section 6(b) of the Executive order, a federalism summary impact statement is not required.

Prior Consultation With State Officials

While FNS did not seek direct consultation with State officials on this proposed rule, FNS staff works with several different States' staff on D–SNAP requests and operations every year. This has provided valuable feedback on the need for flexibility in program design and operations. In addition, FNS regional offices host periodic training meetings and review States' D–SNAP plans. These interactions provide insights into the challenges States face and are reflected in this proposed rule.

Nature of Concerns and the Need To Issue This Rule

The primary intent of this NPRM is to improve clarity for States in their planning for and requests to implement a D–SNAP. This should help ensure timely approval of requests and improved Federal/State coordination in responding to disaster situations. The NPRM is also intended to inform States of their responsibilities in reporting and monitoring D–SNAP. The USDA Office of Inspector General has recommended publication of regulations for the D–SNAP to improve controls over D–SNAP operations and reduce the potential for threats to program integrity.

Extent to Which We Meet Those Concerns

The Department believes that the proposals in this rulemaking would provide the necessary clarity and structure for D–SNAP planning, requests, and reporting while maintaining the needed flexibility for States. In drafting this NPRM, FNS considered its impact on State and local agencies. In addition, the Department is seeking comments on those areas of discretion and will use those comments to inform its decision making before issuing final regulations.

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. This proposed rule, when published as a final rule, is intended to have preemptive effect with respect to any State or local laws, regulations or policies which conflict with its provisions or which would otherwise impede its full implementation. This proposed rule is not intended to have retroactive applicability unless so specified in the "Effective Date" paragraph of the final rule. Prior to any judicial challenge to the provisions of this rulemaking or the application of its provisions, all applicable administrative procedures must be exhausted.

Executive Order 13175

This proposed rule has been reviewed in accordance with the requirements of Executive Order 13175, "Consultation and Coordination with Indian Tribal Governments." Executive Order 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on policies that have tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

FNS has assessed the impact of this proposed rule on Indian tribes and determined that this rule does not, to our knowledge, have Tribal implications that require tribal consultation under EO 13175. On February 18, 2015 the agency held a webinar for tribal participation and comments. During the comment period, FNS did not receive any comments on the proposed rule. If a Tribe requests consultation, FNS will work with the Office of Tribal Relations to ensure meaningful consultation is provided for those changes, additions and modifications identified herein that are not expressly mandated by Congress.

Civil Rights Impact Analysis

FNS has reviewed this proposed rule in accordance with the Department Regulation 4300–4, "Civil Rights Impact Analysis," to identify and address any major civil rights impacts the rule might have on minorities, women, and persons with disabilities. After a careful review of the rule's intent and provisions, and the characteristics of SNAP participants, FNS has determined that an important impact of this proposed rule will be to help alleviate the adverse effects of disasters on certain protected classes. All data available to FNS indicate that protected individuals have the same opportunity to participate in D–SNAP as non-protected individuals. FNS specifically prohibits the State and local government agencies that administer SNAP from engaging in actions that discriminate based on race, color, national origin, gender, age, disability, marital or family status (SNAP's nondiscrimination policy can be found at 7 CFR 272.6 (a)). Where State agencies have options, and they choose to implement a certain provision, they must implement it in such a way that it complies with the regulations at 7 CFR 272.6.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. Chap. 35; see 5 CFR part 1320) requires that the Office of Management and Budget (OMB) approve all collections of information by a Federal agency from the public before they can be implemented. Respondents are not required to respond to any collection of information unless it displays a current valid OMB control number. This proposed rule contains requirements that are subject to review and approval by OMB; therefore, FNS has submitted a new information collection request under OMB Control No: 0584–NEW Supplemental Nutrition Assistance Program (SNAP): Disaster Supplemental Nutrition Assistance Program (D–SNAP) Plans, Procedures, and Reports which contains the proposed reporting burden from adoption of the proposals in the rule, for OMB's review and approval. The estimated burden for the information collections in the proposed rulemaking accompanying this request will be merged into the approved OMB Control Numbers listed in the following sections, contingent upon OMB approval. When the information collection requirements have been approved, FNS will publish a separate action in the **Federal Register** announcing OMB's approval. The D–SNAP certification burden for State participation is included in the currently approved reporting burden under the OMB Control No. 0584–0064, SNAP: Applications, Periodic Reports, and Notices (expiration date: 4/30/2016), which includes all information collection activities associated with the certification of participating and applicant households. Under SNAP regulations, States are responsible for designing their own forms (this burden is included in OMB No. 0584–0064 and will not be duplicated here) including the application for D–SNAP assistance used by individual households. The burden associated with Statewide D–SNAP plans is included in the currently approved burden for OMB Control No. 0584–0083, SNAP: Operating Guidelines, Forms, and Waivers, Program and Budget Summary Statement (expiration date 04/30/2017), which includes all the information collection activities associated with the preparation, review, and submission of updated D–SNAP plans by State agencies. The burden associated with the submission of State agency requests to operate a D–SNAP to FNS is included under the currently approved burden for OMB Control No. 0584–0336, SNAP: Supplemental Nutrition Assistance for Victims of Disaster (expiration date 11/30/2015).

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Send comments to the Office of Information and Regulatory Affairs, OMB, attention: Desk Officer for FNS, Washington, DC 20503. Please also send a copy of your comments to Sasha Gersten-Paal, Branch Chief, Certification Policy Branch, Food and Nutrition Service, U.S. Department of Agriculture, 3101 Park Center Drive, Alexandria, VA 22302. For further information, or for copies of the information collection package, please contact Sasha Gersten-Paal at the above address or via email at *Gersten-Paal@fns.usda.gov.*

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record. These proposed changes are contingent upon OMB approval under the Paperwork Reduction Act of 1995. When the information collection requirements have been approved, FNS will publish a separate action in the **Federal Register** announcing OMB's approval.

Comments on the information collection pursuant to this proposed rule must be received by July 11, 2016.

Title: Supplemental Nutrition Assistance Program (SNAP): Disaster Supplemental Nutrition Assistance Program (D–SNAP) Plans, Procedures, and Reports.

OMB Number: 0584–NEW.

Expiration Date: N/A.

Type of Request: Information Collection Request.

Abstract: The Disaster Relief and Emergency Assistance Act (1974), as amended by the Robert T. Stafford Disaster Relief and Assistance Act (1988) (enclosed), and Section (5)(h) of the Food and Nutrition Act of 2008 (the Act) provides the Secretary of Agriculture with the authority to establish temporary emergency standards of eligibility for households who are survivors of a disaster that disrupts commercial channels of food distribution after those channels have been restored.

This proposed rule would establish the requirements for planning, requesting and monitoring D–SNAP while maintaining State flexibility in program design within the basic eligibility requirements for D–SNAP. This information collection accounts for information that State agencies are required to provide to FNS in support of a request to operate a D–SNAP. As this proposed rule merely codifies practices State agencies already perform, it will have minimal impact on the State agency workloads.

Respondents: 53 State agencies.

Estimated Number of Responses per Respondent: 53 annual reviews of D–SNAP plan; 5 updates of D–SNAP plan; 9 D–SNAP requests; 45 D–SNAP daily reports; 9 D–SNAP post-Disaster reports.

The Department is proposing in this rulemaking that States would be required to review their existing Disaster Plan on at least an annual basis, and when applicable, submit a revision or a notice of no change, by the 15th of August each year. As the majority of States have already prepared disaster plans, the Department estimates that it will take an average of 6.58 staff hours per State each year to review their Disaster Plans, for a total burden of 349 hours (53 States × 1 time annually = 53 total annual response × 6.58 hours = 349 hours). The Department further estimates that on average five of these States will update their plans and require an additional 2.5 hours to do so, for an annual total of 12.5 burden hours. Once approved by OMB, this proposed burden will be merged with the currently approved burden for OMB Control No. 0584–0083, SNAP: Operating Guidelines, Forms, and Waivers, Program and Budget Summary Statement (expiration date 04/30/2017), which includes all the information collection activities associated with the preparation, review, and submission of updated D–SNAP plans by State agencies.

The number of disasters that occur annually and the average number of households affected by the disasters cannot be predicted. For example, during the period from fiscal year 2009 through fiscal year 2014, the number of State requests for disaster programs ranged from 3 to 23 requests per year. However, the Department estimates an average of 9 State agencies will submit 1 D–SNAP request per year to operate D–SNAPs for a total annual request of 9 applications per year. A D–SNAP request normally contains a request to waive the normal SNAP operating procedures and outlines the State's proposed procedures including: Description of incident; geographic area; application period; benefit period; eligibility criteria; currently certified SNAP households eligibility; affected population; electronic benefit card issuance process; logistical plans for D–SNAP rollout; staffing; public information outreach; duplicate participation check process; fraud prevention strategies; and employee application procedures. It is estimated that preparation of a request under the proposed rule will require approximately 10 staff hours for each State, for a total of 90 burden hours. Once approved by OMB, this proposed burden will be merged with the currently approved burden for OMB Control No. 0584–0083, SNAP: Operating Guidelines, Forms, and Waivers, Program and Budget Summary Statement (expiration date 04/30/2017).

In addition, the Department is proposing that States operating a D–SNAP must submit a daily report to FNS. Daily reports are used to monitor progress, troubleshoot problem areas, inform FNS policy officials, ensure that adequate funds are available, and respond to inquiries from the media and other government agencies. The State agency should begin submitting reports on the day following the first day of D–SNAP operations and continue submitting the reports on a daily basis until the end of the application period—typically five days. It is estimated that 0.5 hours will be required to prepare each daily report. Therefore, the burden would be 22.5 total hours for these reports (nine disasters × five reports x 0.5 hours = 22.5). The Department further proposes that a post-disaster report be submitted that includes four parts: a comprehensive review, individual case reviews, problem analysis, and proposed improvements. It is estimated that this report will require 0.5 hours to complete so the total burden for nine disaster reports would be 4.5 hours. FNS will not require a standardized form or specific format for daily reports or post-disaster reports, due to the dynamic nature of emergency situations and the need to quickly respond to conditions on the ground. Once approved by OMB, this proposed burden will be merged with the currently approved burden for OMB Control No. 0584–0083, SNAP: Operating Guidelines, Forms, and Waivers, Program and Budget Summary Statement (expiration date 04/30/2017).

No new recordkeeping burden is estimated.

The average burden per respondent is summarized in the following chart, with an estimated total annual burden of 478 hours. However as noted above, States have been performing many of these practices for years, so the actual new burden would be significantly less.

Section of Regulation	Requirement or burden activity	States responding per year	Responses per respondent	Number of responses	Hours per response	Total burden hours
280.1	Annual review of D–SNAP Plan	53	1	53	6.58	348.7
280.1	Revision of D–SNAP plan	5	1	5	2.5	12.5
280.3	D–SNAP Request	9	1	9	10	90
280.8	D–SNAP Daily report	9	5	45	0.5	22.5
280.8	D–SNAP Post Disaster Report	9	1	9	0.5	4.5
Totals		53	2.28	121	3.95	478

E-Government Act Compliance

FNS is committed to complying with the E-Government Act of 2002 (Pub. L 107–347) to promote the use of the Internet and other information technologies that provide increased opportunities for citizen access to government information and services and for other purposes.

List of Subjects

7 CFR Part 272

Alaska, Civil rights, Supplemental Nutrition Assistance Program, Grant programs—social programs, Penalties, Reporting and recordkeeping requirements, Unemployment compensation, Wages.

7 CFR Part 274

Supplemental Nutrition Assistance Program, Grant programs—social programs, Reporting and recordkeeping requirements.

7 CFR Part 280

Emergency food assistance for victims of disasters.

For reasons set forth in the preamble, 7 CFR parts 272, 274, and 280 are proposed to be amended as follows:

PART 272—REQUIREMENTS FOR PARTICIPATING STATE AGENCIES

■ 1. The authority citation for part 272 continues to read as follows:

Authority: 7 U.S.C. 2011–2036.

■ 2. In § 272.2 revise paragraph (a)(2), (d)(1)(ii), and (e)(5) to read as follows:

§ 272.2 Plan of operation.

(a) * * *

(2) *Content.* The basic components of the State Plan of Operation ("the Plan") are the Federal/State Agreement, the Budget Projection Statement, and the Program Activity Statement. In addition, certain attachments to the Plan are specified in this section and in § 272.3. The requirements for the basic components and attachments are specified in § 272.2(c) and § 272.2(d), respectively. The Federal/State Agreement is the legal agreement between the State and the Department of Agriculture. This Agreement is the means by which the State elects to operate the Supplemental Nutrition Assistance Program and to administer the program in accordance with the Food and Nutrition Act of 2008 and the FNS-approved State Plan of Operation. The Budget Projection Statement and Program Activity Statement provide information on the number of actions and amounts budgeted for various functional areas, such as certification and issuance. The Plan's attachments include the Quality Control Sample Plan, the Disaster Plan, the Employment and Training Plan, the optional Nutrition Education Plan, the optional plan for Program informational activities directed to low-income households, the optional plan for intercepting Unemployment Compensation (UC) benefits for collecting claims for intentional Program violations, the Systematic Alien Verification for Entitlements (SAVE) Plan, and the plan for the State Income and Eligibility Verification System. The State agency shall either include the Workfare Plan in its State Plan of Operation or append the Workfare Plan to the State Plan of Operation, as appropriate, in accordance with § 273.22(b)(3) of this chapter. The Workfare Plan shall be submitted separately, in accordance with § 273.22(b)(1) of this chapter. The ADP/CIS Plan is considered part of the State Plan of Operation but is submitted separately as prescribed under § 272.2(e)(8). State agencies and/or political subdivisions selected to operate a Simplified Application/Standardized Benefit Project shall include that Project's Work Plan in the State Plan of Operation. The Plan's attachments shall also include the Mail Issuance Loss Reporting Level Plan.

* * * * *

(d) * * *

(1) * * *

(ii) Disaster Plan as required by § 280.1(b) of this chapter, or certification that a previously submitted Disaster Plan has been reviewed and remains current;

* * * * *

(e) * * *

(5) *Disaster plan.* State agencies shall review their existing disaster plan on at least an annual basis and submit a revision, if necessary, or a notice of no change, by the 15th of August (or as negotiated by individual states) each year for FNS approval.

* * * * *

PART 274—ISSUANCE AND USE OF PROGRAM BENEFITS

■ 3. The authority citation for part 274 continues to read as follows:

Authority: 7 U.S.C. 2011–2036.

■ 4. Revise § 274.6 (a)(3)(i) to read as follows:

§ 274.6 Replacement issuances and cards to households.

(a) * * *

(3) * * *

(i) Replacement issuances shall be provided only if a household timely reports a loss orally or in writing. When the loss is a Presidentially-declared disaster (with or without individual assistance) the report shall be considered timely if it is made to the State agency within 30 days of the date food purchased with Program benefits is destroyed in the disaster. When the loss is the result of other household misfortune, the report shall be considered timely if it is made to the State agency within 10 days of the date food purchased with Program benefits is destroyed.

* * * * *

PART 280—DISASTER SUPPLEMENTAL NUTRITION ASSISTANCE PROGRAM (D–SNAP)

■ 5. Revise the part heading to read as set out above.

■ 6. Revise part 280 to read as follows:

PART 280—DISASTER SUPPLEMENTAL NUTRITION ASSISTANCE PROGRAM (D–SNAP)

Sec.
280.1 Purpose.
280.2 Eligibility and benefits.
280.3 Disaster request.

280.4 Application processing and certification periods.
280.5 Households participating in the SNAP when D–SNAP is operating.
280.6 Reconciliation.
280.7 Post disaster review and corrections.
280.8 D–SNAP reporting.

Authority: 7 U.S.C. 2011–2036.

§ 280.1 Purpose.

(a) This section establishes the requirements for planning, requesting, operating, and reporting on a D–SNAP. In addition, the appropriate Food and Nutrition Service directives and guidance provide additional detail and direction on the steps States should take to prepare for an emergency situation, and the procedures States should employ in operating D–SNAP.

(b) *Planning for D–SNAP.* State agencies shall review their existing disaster plan on at least an annual basis and submit a revision, if necessary, or a notice of no change, by the 15th of August (or as negotiated by individual states) each year for FNS approval; this submission shall be an attachment of the Plan of Operation as provided in § 272.2 of this chapter. As specified in § 280.8(f), FNS will require State agencies to amend the plan if deficiencies are found in a D–SNAP post-disaster review. The plan shall include:

(1) Identification of Federal and State government agencies involved in disaster relief activities in the State during a disaster, as well as a description of responsibilities for each agency.

(2) *Key points of contact.* Provide names, positions, and phone numbers of county/local, State, and Federal government officials and their back-ups who are key contact persons during a disaster (including the State agency disaster coordinator).

(3) *Community partners.* Identify private disaster relief agencies within the State such as the Red Cross, Salvation Army, or community groups and a description of their role in D–SNAP implementation.

(4) *SNAP staffing and resources.* Identify staffing and related resources available to assist in a disaster and how they will be mobilized to target disaster areas in need. Explain how the State/counties will manage the increased administrative burden associated with running a D–SNAP and SNAP operations simultaneously.

(5) *D–SNAP application system development.* Describe application systems to be used for D–SNAP household management, including any workarounds to the SNAP system, considerations associated with running SNAP and D–SNAP operations concurrently, compliance with D–SNAP reporting requirements, etc.

(6) *Issuance system.* Describe the issuance systems to be used for D–SNAP household management.

(7) *EBT card stock.* Identify EBT card stock available, type of cards to be used, steps and timeline for ordering additional cards, and any special procedures or resources that will be needed to meet SNAP and D–SNAP issuance timeframes, including having cards available at D–SNAP certification sites.

(8) *Application sites.* Describe site selection procedures, including potential application/issuance sites for disasters that vary in size and scope and any agreements in place with those locations. If D–SNAP will operate out of local offices, explain how application sites will handle running D–SNAP and SNAP concurrently.

(9) *Demographic data.* Identify general demographic data that can help the agency tailor its response to a disaster. Identify resources for disaster impact data, including preliminary data assessments, flood maps, or electrical outage data.

(10) *Public information and outreach.* Describe public information strategy to ensure that timely, accurate information reaches households potentially eligible for D–SNAP benefits. Outline roles, expectations, and responsibilities of any SNAP outreach partners included in the State Outreach Plan that will assist with D–SNAP.

(11) *Retailer communication.* Describe procedures to notify retailers of new waivers (see discussion of the potential for hot foods, below) and new D–SNAP households.

(12) *Procedures to reduce applicant hardship.* Outline steps States will take to reduce hardship for D–SNAP applicants and the already certified SNAP caseload, including provisions for security, human needs, language services, etc.

(13) *Certification process.* Describe the specifics of the certification process including potential application sites, staffing, separation of eligibility and issuance, how application sites will manage large crowds, and plans for ensuring access to persons with disabilities, the elderly and other vulnerable populations. If online pre-registrations are to be used by workers or households, describe that process and back-up systems in place if technical issues are encountered.

(14) *DSED.* Include if the DSED will be used and, if so, specify the income limits.

(15) *Household materials.* Include sample household application and household notices.

(16) *Issuance process.* Describe how benefits will be made available within 72 hours of D–SNAP application and how to ensure continuation of SNAP certification, issuance, and other actions concurrently. Indicate how the State will monitor stock levels and ensure sufficient EBT card stock. Describe EBT card reconciliation and security procedures, including tracking D–SNAP benefits separately from SNAP benefit issuance and adherence to FNS reconciliation guidelines, so that benefits posted to accounts can be compared to benefits issued by the State eligibility system.

(17) *Security and fraud prevention plans.* Describe how States will ensure security and mitigate the risk of fraud, including a specific plan for handling applications submitted by State agency employees, procedures for handling questionable applications, and process for checking all household members for duplicate participation.

(18) *Disaster reporting and post-disaster review report.* Describe procedures to ensure that required federal reporting and post-disaster review reports will be complete and timely.

(19) *Reasonable accommodations for individuals with disabilities.* Describe what special accommodations will be made for individuals with disabilities at application and issuance sites.

(20) Circumstances unique to the State which may affect D–SNAP operations, including: coordination of resources among County-level administrations, how to serve isolated or homebound populations, development of procedural modifications to allow SNAP systems to accommodate D–SNAP operations, and contingency plans for local offices located in flood plains or otherwise subject to closure.

(c) *Training.* The State shall issue instructions and provide training to project area offices on the handling of disaster assistance operations to ensure prior understanding of disaster procedures and prompt action upon issuance of a disaster declaration. At a minimum, States shall provide D–SNAP training to at least one manager (perhaps a D–SNAP coordinator) from each SNAP local office and call center in the State.

(d) *State Systems Requirements for D–SNAP.* State automated systems shall have the ability to:

(1) Check for duplicate participation as required in § 280.4(e).

(2) Meet FNS reconciliation requirements that D–SNAP benefits

posted to accounts be compared to benefits issued by the State eligibility system.

(3) Generate the reports required in § 280.8. States systems shall have the ability to track disaster benefits separately from SNAP benefit issuance. States systems shall have the ability to allow tracking of multiple D–SNAPs simultaneously, if the State is struck by two disasters within a short timeframe.

(e) *EBT Systems and D–SNAP.* Each State shall be prepared to issue D–SNAP benefits through its EBT system during a disaster. The EBT system shall have the ability to coordinate with the State's eligibility system and the State's EBT contractor's system. A State's D–SNAP issuance plan shall incorporate procedures for:

(1) Ensuring that approved households have benefits available, including EBT cards and PINs no more than 72 hours from when the application was filed, unless there is questionable information on the application that requires verification. If there is questionable information, the State may extend the 72-hour time frame for making cards and benefits available to no more than a total of seven days from the date of application.

(2) Accessing sufficient EBT card stock to operate a D–SNAP.

(3) Replacing households EBT cards that are lost in a disaster as soon as possible but within the card replacement timeframes required at 7 CFR 274.6(b). If the normal EBT replacement process is to mail the replacement card to the household's home, and the disaster response requires card delivery to a disaster issuance site or alternative address in a non-disaster area, the State must be able to override the EBT system.

§ 280.2 Eligibility and benefits.

(a) *Eligibility.* To be eligible for D–SNAP during a disaster a household must meet all of the following criteria:

(1) At the time of the disaster, the household must have been residing within the geographical area authorized for disaster procedures at the time of the disaster. Such a household may be certified for disaster issuance even though it presently is occupying temporary accommodations outside of the disaster area (although it would need to come to the certification site to be certified for D–SNAP). States may also choose to extend eligibility to those who worked in the disaster area at the time of the disaster. When States submit their D–SNAP requests, they should specify if they will serve only households that lived in the disaster area, or either lived or worked in the disaster area.

(2) The household will purchase food and prepare meals during the disaster benefit period. A household residing in a temporary shelter which is providing all its meals shall be ineligible.

(3) The household has experienced at least one of the following adverse effects of the disaster: loss or inaccessibility of income, inaccessibility of liquid resources, or disaster-related expenses. At the State's option, households whose only disaster-related expense is food loss may be considered otherwise eligible for D–SNAP. States electing this option must indicate it in their D–SNAP request.

(i) Loss or inaccessibility of income involves a reduction or termination of income or a significant delay in receipt of income. This could occur, for example, if a disaster has caused a place of employment to close or reduce its work days, if paychecks or other payments are lost or destroyed, if there is a significant delay in the issuance of paychecks, or if the work location is inaccessible due to the disaster.

(ii) Inaccessibility of liquid resources includes situations in which the household is unable to access cash resources for a portion of the disaster benefit period.

(iii) Regarding disaster-related expenses that the household has incurred during the disaster benefit period that result from the effects of the disaster: the FNS Disaster SNAP Guidance provides the specific expenses that shall be considered disaster-related, but States can request FNS approval of other reasonable expenses in their disaster request.

(b) *Determining income.* (1) To be eligible to receive D–SNAP benefits, a household's net income received or expected to be received during the benefit period, in addition to its accessible liquid resources, minus any disaster-related expenses, shall not exceed the disaster gross income limit.

(2) Accessible liquid resources are determined on the first day of the benefit period; any funds received during the remainder of the benefit period will be counted as income. Accessible liquid resources include cash on hand, and funds in accessible checking and saving accounts on the first day of the benefit period. Accessible liquid resources do not include:

(i) Retirement accounts;

(ii) Disaster insurance payments;

(iii) Disaster assistance received or expected to be received during the benefit period; and

(iv) Payments from Federal, state or county/local government agencies or disaster assistance organizations (including disaster-related Unemployment Compensation).

(3) The most recent disaster gross income limit calculated by FNS shall be used to determine the maximum allowable income for each household size. The disaster gross income limit is calculated by adding together the maximum monthly net income limit, the maximum standard income deduction amount, and the maximum capped shelter expense deduction for each household size.

(c) *D–SNAP deductions.* (1) Disaster-related expenses are deductible if they have been incurred during the disaster period. If the household receives or anticipates receiving a reimbursement for these expenses during the disaster period, only remaining expense amounts shall be deductible.

(2) States shall elect one of the following options to determine if households have disaster-related expenses and the amount of the expense to use in determining D–SNAP income. The option selected shall be identified in the State's D–SNAP request:

(i) Use of actual disaster-related expenses identified in the Disaster SNAP Guidance referenced in paragraph (a)(3)(iii) of this section. Households shall be screened to verify their residence in the affected area. Under this option, the State may require that households experience at least one disaster-related expense other than or in addition to food-loss in order to be eligible for the D–SNAP, while still considering food-loss in calculating a household's cumulative disaster-related expenses. Alternatively, the State may choose to consider households that have experienced food loss alone as their disaster-related expense to be otherwise eligible for the D–SNAP.

(ii) Use of a Disaster Standard Expense Deduction (DSED.) For households with $100 or more in deductible disaster-related expenses, the DSED shall be added to the disaster gross income limit, and households whose take-home pay plus available liquid resources is less than or equal to this amount (DSED + the disaster gross income limit) shall qualify for D–SNAP benefits. The DSED shall not be applied to any household if food loss is their only disaster-related expense.

(3) A State using "food loss alone" in paragraph (c)(2)(i) of this section shall verify using available information such as power outage maps showing affected homes or zip codes. The use of this information should be widely publicized and households shall be

screened upon arrival to verify their residence in the affected area. Households reporting excessively large amounts of food loss, or any other questionable information, shall be referred to fraud investigators or senior staff for further review.

(d) *Benefit period and benefit amount.* (1) Households meeting the eligibility criteria in § 280.2(a) through (c) shall receive the full SNAP allotment for their household size as provided under SNAP. SNAP allotments are updated yearly and available on the FNS Web site. For households already on SNAP and residing in an approved D–SNAP area that incur a disaster-related expense and submit an affidavit to that effect, States shall supplement their SNAP benefits to bring them up to the maximum allotment for their household size.

(2) Household size and composition is established as of the first day of the disaster benefit period. The household includes those people living together, and purchasing and preparing food together at the time of a disaster. D–SNAP household does not include those people with whom applicants are temporarily staying due to the disaster.

(3) The benefit period is the 30-day period approved by FNS for each D–SNAP, except in extraordinary circumstances as determined and approved by FNS. The benefit period is the period during which disaster-related expenses are to be counted; it is also the start date used to determine household composition and resources. Only income received, expenses incurred and resources that are accessible during the benefit period are considered in determining D–SNAP eligibility. The benefit period shall begin on the date of the disaster or the date of any mandatory evacuation preceding the disaster. This date is generally the first day of the "Incident Period" provided by the Presidential Disaster Declaration. State agencies needing to modify dates from those in their approved D–SNAP request must seek FNS approval to do so. States requesting an extension must address the ongoing demand for assistance and program integrity concerns.

§ 280.3 Disaster request.

(a) *Requests for D–SNAP.* (1) The State agency may request authorization from FNS to implement temporary D–SNAP procedures when all or part of a SNAP project area as defined in 7 CFR 271.2 has been struck by a disaster, commercial channels of food distribution are available, there is a Presidentially-declared disaster that includes Individual Assistance (IA), and SNAP cannot respond to the temporary food needs due to the number of affected households.

(2) The request shall be submitted when the affected community and State agency have recovered to allow for an effective administration of the D–SNAP (as determined by the State agency), including training for D–SNAP operations. The request must be submitted to allow for implementation of D–SNAP within a reasonable time period following the Individual Assistance declaration. The planned implementation date shall also allow sufficient time for the State to publicly notify the affected population in the disaster area of the availability of D–SNAP.

(b) *Content of request.* Requests must be submitted with a signed cover memorandum from the State and include thorough explanations of the following components:

(1) A description the disaster—what happened, the date the disaster began, and the affected area.

(2) The geographic area (list of the project areas affected), and explain any differences between the area included in the presidential declaration (if applicable) and the requested area in which to operate the D–SNAP.

(3) A draft press release, sample application, preliminary damage assessments, and map of disaster area. In addition to these required items, other supporting documentation may be included.

(4) The start and end dates of the application period. If the application period will be staggered, give dates for each county/area. Note if application sites will be open over the weekend or for extended hours.

(5) The start and end dates of the 30-day benefit period. The start of the benefit period should generally match the first day of the "incident period" on the disaster declaration. If not, then the State should explain the reason for the difference.

(6) Identification of any options the State has chosen, including whether or not food loss only will be a qualifying expense, and if households that worked but did not live in the disaster area will be eligible.

(7) Whether only households that lived in the disaster area will be eligible for D–SNAP, or if households that only worked in the disaster area will also be eligible.

(8) Whether a DSED is being used. If so, include the income limits.

(9) Whether "food loss alone" will be included as a criterion for eligibility.

(10) Whether supplements will be automatic or individual (by affidavit) for currently certified SNAP households. If automatic, describe who is eligible and include supporting data. Also, indicate an estimate of the value of issuances for automatic supplements. Requests for automatic supplements must be accompanied by supporting data which indicate that a majority of the population in a given area has suffered an adverse effect as a result of the disaster. If individual supplements are to be used, include information on the process for requesting supplements—by phone/mail affidavit, electronically, or in person at local office/D–SNAP application site.

(11) The estimated total number of people, homes, businesses, etc. impacted by the disaster; estimates of anticipated D–SNAP applicants; number of currently certified SNAP households to be served; and explanation of how both estimates were derived.

(12) A description of issuance procedures, the number of EBT cards on hand, and plans for requesting, receiving, and distributing additional cards as needed.

(13) A description of application sites, security/crowd control, and procedures to ensure program access and reasonable accommodation for persons with disabilities.

(14) Plans for utilizing staff from other program areas, counties, or States, as appropriate. Indicate number of staff available and how staff/supervisors will be distributed among the application sites.

(15) A description of how program information, including eligibility criteria and application sites, will be disseminated to the public. List partner organizations involved and describe the responsibilities of each, including role of volunteers, if applicable. Examples of partner activities include spreading D–SNAP information on behalf of the State or providing onsite application assistance. Sufficient time shall be allowed to notify the public prior to the start of the program.

(16) A description of the recipient claim procedures and thresholds to be followed if they differ from either SNAP regulations at § 273.18 of this chapter or the State's FNS approved procedures for handling recipient claims in SNAP.

(17) A description of the procedures that will be used for identifying and handling applications by State agency/State employees.

(18) A description of the fraud prevention strategies and security measures in place.

(c) *Changes to an approved D–SNAP.* (1) When a State believes that a modification to an approved D–SNAP request is necessary, it shall submit a written request to change its approved D–SNAP.

(2) *Expansion of D–SNAP.* To expand the geographic coverage of an approved D–SNAP, a State shall submit a request to FNS for expansion, detailing the impact of the disaster in the new area, the application period, and the anticipated number of applicants and currently certified SNAP households that will be served. If the benefit period will also change, then the new benefit periods dates and justification for doing so shall also be included.

(3) *Extension to a D–SNAP.* In some cases, States may find that their initial application period is not sufficient to serve all eligible households, and they may wish to request that the application period be extended. Requests to extend the D–SNAP application period shall be submitted to FNS with sufficient time for it to review and approve the request prior to the end of the initial application period; requests shall include justification of the need for additional time.

(3) Other Modifications to D–SNAP. Other modifications, including any that would affect applicant eligibility, shall only be made prior to the start of the application period to ensure that the eligibility criteria are applied equitably to all applicants. Occasionally, modifications may be made after D–SNAP operations have begun, such as when a State that was originally approved for individual supplements decides to issue automatic supplements in a certain area. However, once the application period has commenced, the benefit period cannot be modified. Because of the limited window of time in which most modifications can be requested, States should carefully consider their program options prior to submitting the initial request.

§ 280.4 Application processing and certification periods.

(a) *Period for processing applications.* (1) States shall only accept applications for D–SNAP benefits from new households, and requests for supplements from currently certified SNAP households, during the approved application period.

(2) If the State is accepting requests for supplements from currently certified SNAP households over the phone and mailing the affidavit forms to the household, the request for an affidavit must be received during the D–SNAP application period.

(3) Application periods shall last 7 days, though States retain the option to request more or fewer days as they deem appropriate to the circumstances. The State should provide its rationale for any deviation from the 7-day application period in its D–SNAP request. The State should also inform FNS, in its D–SNAP request, whether applications will be accepted on Saturday and/or Sunday.

(b) *Interviews.* (1) All D–SNAP applicants or their authorized representatives are required to have a face-to-face interview. Exceptions to the face-to-face interview shall only be made for individuals with disabilities that preclude visiting an application site. States should use screening techniques prior to the interview to identify those households which do not meet required eligibility criteria, such as having been adversely affected by the disaster. The interview shall be conducted as an official discussion of household circumstances; however, it shall be designed to quickly process the application. If an applicant household does not meet the D–SNAP eligibility standards, the household shall be informed of the potential availability of benefits under SNAP.

(2) The D–SNAP interview shall be conducted by State agency merit system personnel.

(3) The individual interviewed must be a member of the household or an authorized representative. The household may be accompanied to the interview by anyone of its choice. The interviewer shall review the information that appears on the application to resolve unclear or incomplete information with the household.

(c) *Certification period.* Households shall be assigned certification periods that coincide with the disaster benefit period. If the benefit period is one month, then income over this full month period shall be counted, disaster-related expenses that are incurred over this full month period shall be deducted, and the monthly SNAP maximum income limit for the appropriate household size shall equal the disaster eligibility limit. If the disaster benefit period is for half of a month, then income over the half-month period shall be counted, disaster-related expenses incurred over this period shall be deducted, and the disaster eligibility limit shall be one half of the monthly SNAP limit for size of the household.

(d) *Benefit availability.* The State agency shall act promptly on all applications and make benefits available, including EBT cards and PINs, to eligible households that complete the D–SNAP application process no later than 72 hours following their filing of the application, unless the information provided by the applicant is deemed questionable. When information is found to be questionable, the State shall resolve the issue(s) to determine eligibility, and make benefits available within 7 days following the filing of the application or deny the application.

(e) *Screening for duplicate participation during disasters.* States shall develop a system to detect duplicate applications for D–SNAP. States shall either check for duplicate information up front, or may accept applications and inform applicants that eligibility is contingent upon a subsequent check for duplicates. States shall check for duplicate participation using onsite or offsite computer databases, but shall include all individuals included on each application. States shall update computer databases on a daily basis throughout the application period. States shall screen D–SNAP applications for duplicate participation with:

(1) SNAP.

(2) Household disaster distribution of USDA Foods.

(3) Other D–SNAPs with overlapping benefit periods.

(4) Already approved D–SNAP applications.

(5) Denied D–SNAP applicants (to identify attempted duplicate participation).

(f) *D–SNAP verification requirements.* To expedite the certification for D–SNAP, the State agency shall use the procedures specified in this paragraph rather than the standard SNAP verification required by § 273.2(f). The applicant's identity shall be verified. Examples of acceptable verification which the household may provide include, but are not limited to: A driver's license, work or school ID, voter registration card, birth certificate, or, a collateral contact. Residency and household composition at the time of the disaster shall be verified where possible, and must be verified if questionable. In some situations (such as in the case of a household that arrived in the area just prior to the disaster), verification of residency may not be possible. When residency that is questionable cannot be verified despite the efforts of the State agency and the household, the household shall not be denied D–SNAP solely for this reason. Loss/inaccessibility of income or liquid resources and food loss shall be verified if questionable.

(g) *Applications from state and county employees.* State and local staff may be entitled to D–SNAP benefits and shall be subject to the same eligibility criteria as any other applicant. States shall incorporate the following internal controls into their disaster operations.

(1) Certification and issuance duties shall be handled by different staff.

(2) A question shall be included on the D–SNAP application asking if anyone in the applicant household (or its authorized representative) is employed by the State or local SNAP agency.

(3) Supervisors or investigators shall conduct employee certification interviews.

(4) States shall audit all employee applications and inform employees of this policy in advance of implementing the D–SNAP.

§ 280.5 Households participating in the SNAP when D–SNAP is operating.

(a) SNAP shall continue to operate during the disaster benefit period and shall continue to process applications and make eligibility determinations in the normal manner in accordance with parts 273 and 274 of the SNAP regulations in this chapter. Households currently certified for SNAP benefits may be eligible for supplemental benefits.

(b) *Disaster supplements.* (1) When D–SNAP is approved and operating in a given jurisdiction, supplements shall be issued to currently certified SNAP households affected by the disaster in that jurisdiction that bring their benefit level up to the maximum allotment for their household size. States shall issue supplemental benefits on an individual basis, via the filing of an affidavit of disaster loss by the household, or automatically to all currently certified SNAP households in a designated area. By virtue of their participation in SNAP such households need not appear in person at the D–SNAP site.

(2) To obtain an individual supplement, households shall complete an affidavit of disaster loss.

(3) States' requests to issue automatic supplements and the supporting justification shall be included in the State's D–SNAP request. States shall specify their decision to issue automatic supplements and must be able to show that they can effectively target the benefits to geographic areas that were heavily impacted by the disaster. Currently certified SNAP households not receiving automatic issuance but who were living in the disaster area and experienced disaster losses may still request supplemental benefits via an individual affidavit of disaster.

(c) *Replacements.* As provided in § 274.6, replacement benefits are always available to SNAP households that file an affidavit that they have experienced an adverse effect causing them to lose food purchased with their benefits.

§ 280.6 Reconciliation.

(a) *EBT cards.* Cards shipped from a central location shall be tracked until distributed locally to households. Each issuance site shall maintain a beginning and ending inventory and track new cards received, total cards available, and cards issued. If the State assigns Personal Identification Numbers (PINs), they must also account for PIN mailers or envelopes to ensure adequate security, except when the PIN is formulated from the Primary Account Number. The State shall reconcile the number of cards set-up with EBT accounts and the number of cards issued to identify and resolve any discrepancies.

(b) *D–SNAP issuances.* States shall track D–SNAP benefits separately from SNAP benefit issuance and adhere to FNS reconciliation guidelines so that they can compare benefits posted to accounts to benefits issued by the State eligibility system.

§ 280.7 Post disaster review and corrections.

(a) States shall conduct a comprehensive review and individual case reviews. Based upon a problem analysis of the findings from these reviews, the State shall modify its disaster plan.

(1) The comprehensive review should begin with an overview of the D–SNAP operation, including where and when it took place, how it was staffed, and the total number of applications approved and amount of benefits issued. The State should then examine the systems or methods employed, document any major problems or challenges encountered, and discuss the interventions used to solve those issues in the following areas:

(i) Certification systems;
(ii) Fraud control;
(iii) Issuance;
(iv) Public information and outreach;
(v) Program accessibility;
(vi) Security.

(2)(i) The State agency shall conduct a post-disaster review of disaster certification activities by selecting and reviewing a sample of individual cases that applied for D–SNAP. The review of certified cases shall include: A case record review; an interview with the participant; verification of each element of eligibility for the State's D–SNAP program including identity, residency, income, household size and disaster related expenses; a determination of eligibility for disaster assistance; and an analysis of errors.

(ii) States with 10,000 or more approved D–SNAP households shall select a sample of 400 approved cases for review. States with less than 10,000 but more than 300 approved D–SNAP households shall select a sample of between 300 and 400 cases as shown below. States with 300 or fewer would review all cases.

Approved D–SNAP households (N)	Minimum sample size (n)
10,000 and over.	n = 400
300 to 9,999 ...	n = 300 + [0.01031(N − 300)]
Under 300	n = all cases

(iii) A sample of 100 denied D–SNAP applications shall be reviewed to identify errors made in not providing benefits to eligible households. If there are fewer than 100 denied applications, all denied applications would be reviewed.

(iv) If a State uses a random sample, the State shall identify this in the post disaster report described and include the following information:

(A) The number of cases or in the sample universe;
(B) A description of the sample frame and how it was constructed;
(C) The sample size selected;
(D) The number of sample cases completed; and
(E) The findings from the sample cases completed.

(3) States shall review all State agency employee applications—approved and denied.

(4) For all case reviews, no cases shall be dropped for any reason and the State shall report information gathered from all case reviews.

(5) State agencies shall submit the post disaster report containing the results of the reviews, the problem analysis, and proposed improvements within 6 months of the close of each D–SNAP operation.

(b) *Fair hearings requirements in a D–SNAP.* Any household who applied for D–SNAP benefits and was denied may request a fair hearing. A household which has requested a fair hearing shall be offered an immediate onsite supervisory review. Households that are not satisfied with the outcome of the supervisory review retain the right to request a fair hearing in accordance with § 273.15 of this chapter.

(c) *Restored benefits from D–SNAP.* States shall issue restored benefits to households when an incorrect denial of benefits is subsequently corrected. The issuance system shall clearly note that such corrected issuances were restored benefits.

(d) *D–SNAP recipient claims collection requirements.* States shall establish a claim against the household consistent with the claims collection requirements of SNAP regulations at § 273.18 of this chapter. Claims shall be established as soon as possible after the close of the disaster operation. States may also follow their FNS-approved procedures and thresholds for establishing claims in SNAP for claims arising from D–SNAP, or may include any alternate procedures or thresholds in their D–SNAP request. However, if a claim is established against a household for an overpayment of SNAP benefits, this amount may not be collected from the D–SNAP issuance.

§ 280.8 D–SNAP reporting.

(a) *D–SNAP daily reports.* States operating a D–SNAP shall report to FNS on a daily basis. States shall begin submitting reports on the day following the first day of D–SNAP operations and continue submitting the reports on a daily basis until all applications are processed. States shall use a daily reporting template provided by FNS. Data should be submitted by county, as indicated in the template. The daily reports must capture the new D–SNAP and SNAP issuance data listed in paragraphs (a)(1) through (13) of this section:

(1) Number of D–SNAP applications received;

(2) Number of new D–SNAP households approved;

(3) Number of new D–SNAP persons approved;

(4) Number of SNAP households receiving supplements;

(5) Number of people previously certified for SNAP approved for supplements;

(6) Number of new D–SNAP households denied;

(7) Number of SNAP households receiving replacement issuance;

(8) Value of new D–SNAP benefits approved;

(9) Value of SNAP supplements approved;

(10) Value of SNAP replacement issuance;

(11) Average benefit per new D–SNAP household;

(12) Average benefit per SNAP household; and

(13) Any additional information the State believes FNS should be aware of.

(b) *FNS–292B, Report of Supplemental Nutrition Assistance Program Benefit Issuance for Disaster Relief.* Within 45 days of the termination of a D–SNAP operation, the State agency shall submit the FNS–292B. This report shall be submitted electronically in the Food Programs Reporting System (FPRS). The FNS 292B shall contain the following issuance data for D–SNAP operations:

(1) Number of new households issued D–SNAP benefits.

(2) Total number of new persons issued D–SNAP benefits.

(3) Number of households certified in SNAP that were issued supplements.

(4) Total value of benefits issued to new households and supplements issued to previously certified SNAP households.

(c) *Form FNS–388, Monthly Issuance Report.* The FNS–388 shall include issuance and participation figures for new D–SNAP households and previously certified SNAP households receiving disaster supplements and/or replacements. Replacement benefits shall be reported for the month for which they are intended.

(d) *Form FNS–209, Status of Claims Against Households Report.* In the remarks section of the FNS–209, States shall indicate the number of claims established and collected against D–SNAP benefits. D–SNAP claims must be identified on backup documentation in the accounting systems for the FNS–209.

(e) *Form FNS–46, Issuance Reconciliation Report.* The FNS–46 shall include issuance and participation figures for new D–SNAP households and SNAP households receiving disaster supplements and/or replacements. The FNS–46 and FNS–388 should reconcile with the reported net issuance.

(f) *Post-disaster Report.* The post-disaster review report shall be comprised of four parts: The comprehensive review, individual reviews, problem analysis, and proposed improvements to the disaster plan. States shall submit the post-disaster report containing the reviews, the problem analysis, and proposed improvements within 6 months of the close of each D–SNAP operation.

Dated: May 2, 2016.

Telora T. Dean,

Acting Administrator, Food and Nutrition Service.

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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 319

[Docket No. APHIS–2014–0092]

RIN 0579–AE17

Importation of Lemons From Northwest Argentina

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the fruits and vegetables regulations to allow the importation of lemons from northwest Argentina into the continental United States. As a condition of entry, lemons from northwest Argentina would have to be produced in accordance with a systems approach that would include requirements for importation in commercial consignments; registration and monitoring of places of production and packinghouses; pest-free places of production; grove sanitation, monitoring, and pest control practices; treatment with a surface disinfectant; lot identification; and inspection for quarantine pests by the Argentine national plant protection organization. Additionally, lemons from northwest Argentina would have to be harvested green and within a certain time period, or treated for Medfly in accordance with an approved treatment schedule. Lemons from northwest Argentina would also be required to be accompanied by a phytosanitary certificate with an additional declaration stating that the lemons have been inspected and found to be free of quarantine pests and were produced in accordance with the proposed requirements. This action would allow for the importation of lemons from northwest Argentina into the United States while continuing to provide protection against the introduction of quarantine pests.

DATES: We will consider all comments that we receive on or before July 11, 2016.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0092.*
- *Postal Mail/Commercial Delivery:* Send your comments to Docket No. APHIS–2014–0092, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0092* or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: Mr. Juan A. (Tony) Román, Senior Regulatory Policy Specialist, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737–1236; (301) 851–2242.

SUPPLEMENTARY INFORMATION:

Background

The regulations in "Subpart–Fruits and Vegetables" (7 CFR 319.56–1 through 319.56–75, referred to below as the regulations) prohibit or restrict the importation of fruits and vegetables into the United States from certain parts of the world to prevent the introduction and dissemination of plant pests within the United States.

The national plant protection organization (NPPO) of Argentina has requested that the Animal and Plant Health Inspection Service (APHIS) amend the regulations to allow lemons (*Citrus limon* L.) from the northwest region of Argentina (the Provinces of Catamarca, Jujuy, Salta, and Tucumán) to be imported into the continental United States. Northwest Argentina is the main lemon-producing region in Argentina, and different pests occur there than those that occur in other citrus-producing areas in Argentina.

In evaluating Argentina's request, we prepared a pest risk assessment (PRA) and risk management document (RMD). Copies of the PRA and the RMD may be obtained from the person listed under **FOR FURTHER INFORMATION CONTACT**, viewed in the reading room listed above under **ADDRESSES**, or viewed on the Regulations.gov Web site (see **ADDRESSES** above for instructions for accessing Regulations.gov).

The PRA, titled "Risk Assessment for the Importation of Fresh Lemon (*Citrus limon* (L.) Burm. f.) Fruit from Northwest Argentina into the Continental United States" analyzes the potential pest risk associated with the importation of fresh lemons into the continental United States from northwest Argentina.

A quarantine pest is defined in § 319.56–2 of the regulations as a pest of potential economic significance to the area endangered thereby and not yet present there, or present but not widely distributed and being officially controlled. The PRA identifies nine pests of quarantine significance present in Argentina that could follow the pathway for lemons from northwest Argentina to the continental United States. They are:

- *Brevipalpus californicus* (Banks), the citrus flat mite; *B. obovatus* Donnadieu, the scarlet tea mite; and *B. phoenicis* (Geijskes), the false spider mite. These mites (referred to in this document as the *Brevipalpus* spp. mites) are potential vectors of citrus leprosis virus (CiLV), a quarantine pest present in Argentina;
- *B. chilensis* Baker, the Chilean false red mite;
- *Ceratitis capitata* (Wiedemann), the Mediterranean fruit fly (Medfly);
- *Cryptoblabes gnidiella* (Millière), the honeydew moth;
- *Elsinoë australis* Bitanc. & Jenkins 1936, the causal agent of sweet orange scab disease (SOS);
- *Gymnandrosoma aurantianum* (Lima), the citrus borer; and
- *Xanthomonas citri* subsp. *citri* (ex Hasse) Gabriel et al. 1989, the causal agent of citrus canker disease (Xcc).

The PRA derives plant pest risk potentials for these pests by estimating the likelihood of introduction of each pest into the continental United States through the importation of lemons from northwest Argentina. The PRA considers four of the pests to have a high pest risk potential (*B. chilensis, C. capitata, C. gnidiella,* and *G. aurantianum),* and five to have a medium risk potential (the *Brevipalpus* spp. mites, *E. australis,* and Xcc).

Based on the findings of the PRA, APHIS has determined that measures beyond standard port-of-entry inspection are necessary in order to mitigate the risk associated with the importation of fresh lemons from northwest Argentina into the continental United States. These measures are listed in the RMD and are used as the basis for the requirements of this proposed rule.

Therefore, we are proposing to amend the regulations to allow the importation of commercial consignments of fresh lemons from northwest Argentina into the continental United States, subject to a systems approach. Requirements of the systems approach, which would be added to the regulations as a new § 319.56–76, are discussed in the following sections.

Proposed Systems Approach

General Requirements

Proposed paragraph (a) of § 319.56–76 would set out general requirements for fresh lemons from northwest Argentina destined for export to the continental United States.

Proposed paragraph (a)(1) of § 319.56–76 would require the NPPO of Argentina to provide an operational workplan to APHIS that details the systems approach activities that the NPPO of Argentina and places of production and packinghouses registered with the NPPO of Argentina would, subject to APHIS approval of the workplan, implement to meet the proposed requirements. An operational workplan is an arrangement between APHIS' Plant Protection and Quarantine program and officials of the NPPO of a foreign government that specifies in detail the phytosanitary measures that will comply with U.S. regulations governing the import or export of a specific commodity. Operational workplans apply only to the signatories and establish detailed procedures and guidance for the day-to-day operations of specific import/export programs. Operational workplans also establish how specific phytosanitary issues are dealt with in the exporting country and make clear who is responsible for dealing with those issues. Operational workplans require APHIS approval.

If the operational workplan is approved, APHIS would be directly involved with the NPPO of Argentina in monitoring and auditing the systems approach implementation. Such monitoring could involve site visits by APHIS personnel.

Proposed paragraph (a)(2) of § 319.56–76 would require the lemons considered for export to the continental United States to be grown by places of production that are registered with the NPPO of Argentina and that have been determined to be free from *B. chilensis* in accordance with the proposed regulations. We discuss the proposed protocol for considering a production site free from *B. chilensis* later in this document.

Proposed paragraph (a)(3) of § 319.56–76 would require the lemons to be packed for export to the continental United States in pest-exclusionary packinghouses that are registered with the NPPO of Argentina.

Registration of places of production and packinghouses with the NPPO of Argentina would ensure that the NPPO exercises oversight of these locations and that the places of production and packinghouses continuously follow the provisions of the export program. It would also facilitate traceback in the event that lemons from Argentina are determined to be infested with quarantine pests.

Proposed paragraph (a)(4) of § 319.56–76 would require the NPPO of Argentina to maintain all forms and documents pertaining to registered places of production and packinghouses for at least 1 year and, as requested, provide them to APHIS for review. Such forms and documents would include (but would not be limited to) records regarding fruit fly trapping in registered places of production and records regarding pest detections in registered places of production and registered packinghouses. Based on APHIS' review of the records, we may monitor places of production and packinghouses, as we deem warranted.

Proposed paragraph (a)(5) of § 319.56–76 would require lemons from Argentina to be imported into the continental United States in commercial consignments only. Noncommercial shipments are more prone to infestations because the commodity is often ripe to overripe, could be of a variety with unknown susceptibility to pests, and is often grown with little or no pest control. Commercial consignments, as defined in § 319.56–2 of the regulations, are consignments that an inspector identifies as having been imported for sale and distribution. Such identification is based on a variety of indicators, including, but not limited to: Quantity of produce, type of packaging, identification of place of production or packinghouse on the packaging, and documents consigning the fruits or vegetables to a wholesaler or retailer. For purposes of the proposed regulations, in order for a consignment to be considered a commercial consignment, fruit in the consignment would have to be practically free of leaves, twigs, and other plant parts, except for stems less than 1 inch long and attached to the fruit. We currently require most other fruits and vegetables imported into the United States from foreign countries to be imported in commercial consignments as a mitigation against quarantine pests of those commodities.

Proposed paragraph (a)(6) of § 319.56–76 would require the identity of each lemon from Argentina destined for export to the continental United States to be maintained throughout the export process, from the place of production to the arrival at the port of entry in the continental United States. The operational workplan would have to authorize the means of identification used that allows the lot to be traced back to its place of production. This requirement would facilitate traceback in the event that quarantine pests are discovered in a lot of lemons destined for export to the United States. This, in turn, would help ensure that timely remedial measures are taken to address the plant pest risk at the place of production and preclude the further export of infested fruit from that place of production.

Proposed paragraph (a)(7) of § 319.56–76 would require lemons from Argentina to be harvested green and within the time period of April 1 and August 31. If the lemons are harvested yellow or harvested outside of that time period, they would have to be treated for Medfly in accordance with 7 CFR part 305 and the operational workplan. As documented in the RMD, lemons are a poor host of Medfly, and research has shown that harvesting them green during that time period, when Medfly populations are low in Argentina, is an effective mitigation against Medfly.

Within part 305, § 305.2 provides that approved treatment schedules for Medfly and other quarantine pests are set forth in the Plant Protection and Quarantine Treatment Manual, found online at *http://www.aphis.usda.gov/import_export/plants/manuals/ports/downloads/treatment.pdf.* The manual currently specifies that cold treatment according to schedule T107-a is effective in neutralizing Medfly on citrus. If lemons from Argentina are harvested yellow, or outside of the prescribed time period, they would have to be treated according to this approved schedule.

Proposed paragraph (a)(8) of § 319.56–76 would provide that lots of lemons destined for export to the continental United States must be safeguarded during movement from registered places of production to registered packinghouses as specified by the operational workplan. Such safeguarding could include the use of pest-proof screens or tarpaulins to cover the lots during transit, or other similar measures approved by APHIS and the NPPO of Argentina.

Proposed paragraph (a)(9) of § 319.56–76 would require each consignment of lemons imported from Argentina into the continental United States to be accompanied by a phytosanitary certificate issued by the NPPO of Argentina with an additional declaration stating that the requirements in the proposed regulations have been met and consignments have been inspected and found free of *Brevipalpus* spp. mites, *B. chilensis, C. capitata, C. gnidiella,* and *G. aurantianum.*

Place of Production Requirements

The proposed systems approach would require places of production to meet certain requirements and take certain measures to prevent the introduction of quarantine pests to lemons destined for export to the continental United States. Proposed paragraph (b) of § 319.56–76 would contain these requirements and measures.

Proposed paragraph (b)(1) of § 319.56–76 would require that, prior to each harvest season, registered places of production of lemons destined for export to the continental United States must be determined by APHIS and the NPPO of Argentina to be free from *B. chilensis* based on biometric sampling conducted in accordance with the operational workplan. If a single *B. chilensis* mite is discovered as a result of such sampling, the place of production would not be considered free from *B. chilensis* for that harvest season. Each place of production would have only one opportunity per harvest season to be considered free of *B. chilensis,* and certification of *B. chilensis* freedom would only last one harvest season.

Currently, APHIS authorizes the importation of several commodities from Chile, including kiwi, clementines, mandarins, and tangerines, subject to confirmation, using a similar sampling method, that places of production for those commodities have a low prevalence for *B. chilensis.* The biometric sampling used to establish freedom from *B. chilensis* would be modeled on the sampling protocols currently used in Chile to establish places of production of low pest prevalence for *B. chilensis.*

Under the proposed biometric sampling protocol, between 1 and 30 days before harvest, 100 random samples of fruit would have to be collected from each registered place of production. The samples would then have to washed, placed on a mesh sieve, sprinkled with liquid soap and water solution, washed with water at high pressure, and washed with water at lower pressure. Once this cleaning process is repeated twice, the contents of the sieves would have to be placed on a petri dish and examined for *B. chilensis.*

Proposed paragraph (b)(2) of § 319.56–76 would require registered places of production to remove plant litter and fallen debris from groves in accordance with the operational workplan. It would also prohibit fallen fruit from being included in field containers of fruit brought to the packinghouse to be packed for export. Plant litter, fallen debris, and fallen fruit are especially susceptible to quarantine pests.

Proposed paragraph (b)(3) of § 319.56–76 would require registered places of production to trap for Medfly in accordance with the operational workplan. The operational workplan would specify the types of traps and baits that must be used, the minimum number of traps per acre that must be deployed, the requisite distance between each trap, and the intervals at which the traps must be serviced. The NPPO would have to keep records regarding the placement and monitoring of all traps, as well as records of all pest detections in these traps, and provide the records to APHIS, as requested.

Proposed paragraph (b)(4) of § 319.56–76 would require registered places of production to carry out any additional grove sanitation and phytosanitary measures specified for the place of production by the operational workplan. Depending on the location, size, and plant pest history of the grove, these could include surveying protocols, safeguarding of trees, application of pesticides and fungicides, or other measures.

Proposed paragraph (b)(5) of § 319.56–76 would require the NPPO of Argentina to visit and inspect registered places of production regularly for signs of infestations and to allow APHIS to monitor these inspections. These inspections would have to start no more than 30 days before harvest and continue until the end of the export season.

Proposed paragraph (b)(6) of § 319.56–76 would provide that if APHIS or the NPPO of Argentina determines that a registered place of production has failed to follow the requirements of the regulations, the place of production would be excluded from the export program until APHIS and the NPPO of Argentina jointly agree that the place of production has taken appropriate remedial measures to address the plant pest risk.

Packinghouse Requirements

Proposed paragraph (c) of § 319.56–76 would set forth requirements for mitigation measures that would have to occur at registered packinghouses.

Proposed paragraph (c)(1) of § 319.56–76 would require that, while a registered packinghouse is in use for packing lemons for export to the continental United States, the packinghouses may only accept lemons that are from registered places of production and that have been produced in accordance with proposed § 319.56–76. Lemons from other places of production may be produced under conditions that are less stringent than those of this proposed rule, and may therefore be a pathway for the introduction of quarantine pests into the packinghouses.

Proposed paragraph (c)(2) of § 319.56–76 would require lemons to be packed within 24 hours of harvest in a registered pest-exclusionary packinghouse or stored in a degreening chamber in the registered pest-exclusionary packinghouse. The lemons would have to be packed for shipment to the continental United States in insect-proof cartons or containers, or covered with insect-proof mesh or plastic tarpaulin. These safeguards would have to remain intact until the lemons arrive in the United States, or the consignment would not be allowed to enter the United States. These requirements collectively would aid in preventing the lemons from becoming infested with plant pests during or subsequent to packing.

Proposed paragraph (c)(3) of § 319.56–76 would require the lemons to be washed, brushed, and surface disinfected for *E. australis* and Xcc in accordance with the operational workplan, treated with an APHIS-approved fungicide, and waxed. Section 301.75–7 requires citrus fruit from areas of the United States that are quarantined for Xcc to be treated at packinghouses for Xcc. Additionally, a December 2010 Federal Order for the interstate movement of citrus fruit from areas of the United States that are quarantined for *E. australis* requires the fruit to be washed, disinfected, treated, and waxed at packinghouses in order for a certificate to be issued authorizing the unrestricted interstate movement of the fruit within the United States.[1] Accordingly, this requirement would be generally consistent with current domestic requirements.

Proposed paragraph (c)(4) of § 319.56–76 would require the NPPO of Argentina or officials authorized by the NPPO of Argentina to visually inspect a biometric sample of each consignment for quarantine pests, wash the lemons in the sample, and inspect the filtrate for *B. chilensis* in accordance with the operational workplan. In addition to identifying lemons infested with *B. chilensis,* this method of visual inspection would be able to detect any signs or symptoms of *Brevipalpus* spp. mites on the lemons.

A portion of the fruit would then have to be cut open and inspected for evidence of quarantine pests. Cutting the fruit open would allow inspectors to determine whether the fruit is infested with Medflies or *C. gnidiella* or *G. aurantianum* larvae.

If a single *C. gnidiella* or G. *aurantianum* in any stage of development is found on the lemons, the entire consignment would be prohibited from export to the United States, and the registered place of production that produced the lemons would be suspended from the export program until APHIS and the NPPO of Argentina jointly agree that the place of production has taken appropriate remedial measures to address plant pest risk.

If a single *B. chilensis* or *Brevipalpus* spp. mite in any stage of development is found on the lemons, the entire consignment would be prohibited from export, and the registered place of production that produced the lemons may be suspended from the export program, pending an investigation.

If a single immature Medfly is found in or with the lemons, the lemons would have to be treated in accordance with 7 CFR part 305 and the operational workplan, and the registered place of production that produced the lemons in the consignment may be suspended from the export program, pending an investigation.

We would not require remedial measures to be taken if fruit is determined to be symptomatic for *E. australis* or Xcc because we have determined that fruit that is symptomatic for these pathogens and that has been subject to the treatment and processing protocol specified in proposed paragraph (c)(3) of § 319.56–76 is not a pathway for the spread of the pathogens. This is reflected in our conditions for the interstate movement of citrus fruit that is symptomatic for *E. australis* or Xcc.

Proposed paragraph (c)(5) of § 319.56–76 would provide that, if APHIS or the NPPO of Argentina determines that a registered packinghouse has failed to follow the requirements of the regulations, the packinghouse would be excluded from the export program until APHIS and the NPPO of Argentina jointly agree that the packinghouse has taken appropriate remedial measures to address the plant pest risk.

Port of Entry Requirements

Proposed paragraph (d) of § 319.56–76 would provide that consignments of lemons from Argentina will be inspected at the port of entry to the United States, and that, if any quarantine pests are discovered on the lemons during this inspection, the entire lot in which the quarantine pest was discovered would be subject to appropriate remedial measures to address this risk.

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[1] To view the Federal Order, go to *http://www.aphis.usda.gov/plant_health/plant_pest_info/citrus/downloads/sweet_orange/2010-62.pdf.*

Miscellaneous Amendments to § 319.28

The regulations in § 319.28(a) prohibit the importation of citrus from Argentina, as well as from eastern and southeastern Asia, Japan, Brazil, Paraguay, and other designated areas. However, paragraphs (b) through (e) of § 319.28 set out various exceptions to this prohibition. To allow the importation of lemons from northwestern Argentina under § 319.56–76, we propose adding a new paragraph (e) to § 319.28 stating that the prohibition does not apply to lemons from northwest Argentina that meet the requirements of § 319.56–76. To accommodate the addition of the new paragraph (e) in § 319.28, we would redesignate current paragraphs (e) through (i) as (f) through (j), respectively.

Paragraph (a)(1) of § 319.28 provides that importation of fruits and peels of the genera and varieties listed in that paragraph is allowed from the Provinces[2] of Catamarca, Jujuy, Salta, and Tucumán in Argentina because those Provinces are considered to be free of Xcc. However, we now consider Xcc to be present in those Provinces. Therefore, we would remove that statement.

Finally, paragraph (a)(2) of § 319.28 currently prohibits the importation of lemons from Argentina, among other countries, to prevent the introduction of SOS within the United States. We would remove this prohibition.

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

We have prepared an economic analysis for this rule. The economic analysis provides a cost-benefit analysis, as required by Executive Order 12866, and an initial regulatory flexibility analysis that examines the potential economic effects of this proposed rule on small entities, as required by the Regulatory Flexibility Act. The economic analysis is summarized below. Copies of the full analysis are available by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**, in the reading room (see **ADDRESSES** above for more information), or on the Regulations.gov Web site (see **ADDRESSES** above for instructions for accessing Regulations.gov).

The analysis examines potential economic impacts on small domestic entities of allowing the importation of fresh lemons from northwest Argentina into the continental United States. A systems approach to pest risk mitigation would provide phytosanitary protection against pests of quarantine significance. Economic effects of the rule for both U.S. producers and consumers are not expected to be significant. While producers' welfare would be negatively affected, welfare gains for consumers would outweigh producer losses, resulting in a net benefit to the U.S. economy.

In the United States, commercial lemon production takes place in California and Arizona. For the 2013/14 season, lemon-bearing acres totaled 54,500 (California 46,000, Arizona 8,500). In the same season, the value of U.S. production of lemons was $647 million, 92 percent earned by California's growers and 8 percent by Arizona's growers. Over the five seasons, 2008/09 to 2012/13, U.S. fresh lemon production averaged about 497,350 metric tons (MT) per year. Over the same period, annual imports averaged about 45,751 MT and exports averaged about 95,574 MT. Because of the provisions of the rule, we expect that most lemons will be exported from April 1 to August 31, a period that coincides roughly with the months in which U.S. lemon exports are declining and imports are increasing.

Effects of the proposed rule are estimated using a partial equilibrium model of the U.S. lemon sector. Annual imports of fresh lemon from Argentina are expected to range between 15,000 and 20,000 MT, with volumes averaging 18,000 MT. Quantity, price, and welfare changes are estimated for these three import scenarios.

If the United States were to import 18,000 MT of fresh lemon from Argentina and there were no displacement of lemon imports from other countries, the price would decrease by an estimated 4 percent. Consumer welfare gains of about $25 million would outweigh producer welfare losses of about $22 million, resulting in a net welfare gain of about $3 million. The 15,000 MT and 20,000 MT scenarios show similar effects.

More reasonably, partial import displacement would occur, and price and welfare effects would be proportional to the net increase in U.S. lemon imports. If one-half of the quantity of fresh lemon imported from Argentina were to displace U.S. fresh lemon imports from elsewhere, then for the 18,000 MT scenario the price decline would be about 2 percent; consumer welfare gains and producer welfare losses would be about $12.2 million and $10.9 million, respectively, yielding a net welfare benefit of about $1.3 million.

The majority of businesses that may be affected by the proposed rule are small entities, including lemon producers, packers, wholesalers, and related establishments. APHIS welcomes public comment in order to better determine the extent to which U.S. small entities may be affected by this proposed rule.

Executive Order 12988

This proposed rule would allow lemons to be imported into the continental United States from northwest Argentina. If this proposed rule is adopted, State and local laws and regulations regarding lemons imported under this rule would be preempted while the fruit is in foreign commerce. Fresh lemons are generally imported for immediate distribution and sale to the consuming public and would remain in foreign commerce until sold to the ultimate consumer. The question of when foreign commerce ceases in other cases must be addressed on a case-by-case basis. If this proposed rule is adopted, no retroactive effect will be given to this rule, and this rule will not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB). Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. Please state that your comments refer to Docket No. APHIS–2014–0092. Please send a copy of your comments to: (1) Docket No. APHIS–2014–0092, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238, and (2) Clearance Officer, OCIO, USDA, Room 404–W, 14th Street and Independence Avenue SW., Washington, DC 20250.

This proposed rule would allow the importation of lemons from northwest Argentina that have been produced in accordance with the requirements of a systems approach. This action would require information collection activities, such as an operational workplan, production site and packinghouse registration and recertification, pest-free determination, recordkeeping, monitoring of traps, NPPO inspection, identification, treatment records, and a phytosanitary certificate.

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[2] The paragraph currently refers to these administrative units as "States." However, as noted within this document, administrative units within Argentina are Provinces, not States.

We are soliciting comments from the public (as well as affected agencies) concerning our proposed information collection and recordkeeping requirements. These comments will help us:

(1) Evaluate whether the proposed information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond (such as through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology; *e.g.,* permitting electronic submission of responses).

Estimate of burden: Public reporting burden for this collection of information is estimated to average 0.07356 hours per response.

Respondents: Producers, importers of lemons, the NPPO of Argentina.

Estimated annual number of respondents: 76.

Estimated annual number of responses per respondent: 52.40.

Estimated annual number of responses: 3,983.

Estimated total annual burden on respondents: 293 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

Copies of this information collection can be obtained from Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851–2727.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the EGovernment Act to promote the use of the Internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this proposed rule, please contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851–2727.

List of Subjects for 7 CFR Part 319

Coffee, Cotton, Fruits, Imports, Logs, Nursery stock, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Rice, Vegetables.

Accordingly, we propose to amend 7 CFR part 319 as follows:

PART 319—FOREIGN QUARANTINE NOTICES

■ 1. The authority citation for part 319 continues to read as follows:

Authority: 7 U.S.C. 450, 7701–7772, and 7781–7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

■ 2. Section 319.28 is amended as follows:

■ a. In paragraph (a)(1), by removing the words "(except for the States of Catamarca, Jujuy, Salta, and Tucumán, which are considered free of citrus canker)".

■ b. In paragraph (a)(2), by removing the word "Argentina,".

■ c. By redesignating paragraphs (e) through (i) as paragraphs (f) through (j), respectively, and adding a new paragraph (e).

The addition reads as follows:

§ 319.28 Notice of quarantine.

* * * * *

(e) The prohibition does not apply to lemons (*Citrus limon* (L.) Burm. f.) from northwest Argentina that meet the requirements of § 319.56–76.

* * * * *

■ 5. Section 319.56–76 is added to read as follows:

§ 319.56–76 Lemons from northwest Argentina.

Fresh lemons (*Citrus limon* (L.) Burm. f.) may be imported into the continental United States from northwest Argentina (the Provinces of Catamarca, Jujuy, Salta, and Tucumán) only under the conditions described in this section. These conditions are designed to prevent the introduction of the following quarantine pests: *Brevipalpus chilensis,* the Chilean false red mite; *B. californicus,* the citrus flat mite, *B. obovatus,* the scarlet tea mite, and *B. phoenicis,* the false spider mite (referred to in this section as "*Brevipalpus* spp. mites"); *Ceratitis capitata,* the Mediterranean fruit fly; *Cryptoblabes gnidiella,* the honeydew moth; *Elsinoë australis,* the causal agent of sweet orange scab disease; *Gymnandrosoma aurantianum* (Lima), the citrus borer; and *Xanthomonas citri* subsp. *citri* (ex Hasse) Gabriel et al., the causal agent of citrus canker disease.

(a) *General requirements*—(1) *Operational workplan.* The national plant protection organization (NPPO) of Argentina must provide an operational workplan to APHIS that details the activities that the NPPO of Argentina and places of production and packinghouses registered with the NPPO of Argentina will, subject to APHIS' approval of the workplan, carry out to meet the requirements of this section. The operational workplan must include and describe the specific requirements as set forth in this section. APHIS will be directly involved with the NPPO of Argentina in monitoring and auditing implementation of the systems approach.

(2) *Registered places of production.* The fresh lemons considered for export to the continental United States must be grown by places of production that are registered with the NPPO of Argentina and that have been determined to be free from *B. chilensis* in accordance with this section.

(3) *Registered packinghouses.* The lemons must be packed for export to the continental United States in pest-exclusionary packinghouses that are registered with the NPPO of Argentina.

(4) *Recordkeeping.* The NPPO of Argentina must maintain all forms and documents pertaining to registered places of production and packinghouses for at least 1 year and, as requested, provide them to APHIS for review. Based on APHIS' review of records, APHIS may monitor places of production and packinghouses, as APHIS deems warranted.

(5) *Commercial consignments.* Lemons from Argentina can be imported to the continental United States in commercial consignments only. For purposes of this section, fruit in a commercial consignment must be practically free of leaves, twigs, and other plant parts, except for stems less than 1 inch long and attached to the fruit.

(6) *Identification.* The identity of the each lot of lemons from Argentina must be maintained throughout the export process, from the place of production to the arrival of the lemons at the port of entry into the continental United States. The means of identification that allows the lot to be traced back to its place of production must be authorized by the operational workplan.

(7) *Harvesting restrictions or treatment for fruit flies.* Lemons from Argentina must be harvested green and within the time period of April 1 and August 31. If they are harvested yellow

or harvested outside of this time period, they must be treated for *C. capitata* in accordance with part 305 of this chapter and the operational workplan.

(8) *Safeguarding.* Lots of lemons destined for export to the continental United States must be safeguarded during movement from registered places of production to registered packinghouses as specified by the operational workplan.

(9) *Phytosanitary certificate.* Each consignment of lemons imported from Argentina into the continental United States must be accompanied by a phytosanitary certificate issued by the NPPO of Argentina with an additional declaration stating that the requirements of this section have been met and that the consignments have been inspected and found free of *Brevipalpus* spp. mites, *B. chilensis, C. capitata, C. gnidiella,* and *G. aurantianum.*

(b) *Place of production requirements.* (1) Prior to each harvest season, registered places of production of lemons destined for export to the continental United States must be determined by APHIS and the NPPO of Argentina to be free from *B. chilensis* based on biometric sampling conducted in accordance with the operational workplan. If a single live *B. chilensis* mite is discovered as a result of such sampling, the place of production will not be considered free from *B. chilensis.* Each place of production will have only one opportunity per harvest season to be considered free of *B. chilensis,* and certification of *B. chilensis* freedom will only last one harvest season.

(2) Places of production must remove plant litter and fallen debris from groves in accordance with the operational workplan. Fallen fruit may not be included in field containers of fruit brought to the packinghouse to be packed for export.

(3) Places of production must trap for *C. capitata* in accordance with the operational workplan. The NPPO must keep records regarding the placement and monitoring of all traps, as well as records of all pest detections in these traps, and provide the records to APHIS, as requested.

(4) Places of production must carry out any additional grove sanitation and phytosanitary measures specified for the place of production by the operational workplan.

(5) The NPPO of Argentina must visit and inspect registered places of production regularly throughout the exporting season for signs of infestations. These inspections must start no more than 30 days before harvest and continuing until the end of the export season. The NPPO of Argentina must allow APHIS to monitor these inspections. The NPPO of Argentina must also provide records of pest detections and pest detection practices to APHIS. Before any place of production may export lemons to the continental United States pursuant to this section, APHIS must review and approve of these practices.

(6) If APHIS or the NPPO of Argentina determines that a registered place of production has failed to follow the requirements in this paragraph (b), the place of production will be excluded from the export program until APHIS and the NPPO of Argentina jointly agree that the place of production has taken appropriate remedial measures to address the plant pest risk.

(c) *Packinghouse requirements.* (1) During the time registered packinghouses are in use for packing lemons for export to the continental United States, the packinghouses may only accept lemons that are from registered places of production and that have been produced in accordance with the requirements of this section.

(2) Lemons destined for export to the continental United States must be packed within 24 hours of harvest in a registered pest-exclusionary packinghouse or stored in a degreening chamber in the registered pest-exclusionary packinghouse. Lemons must be packed for shipment to the continental United States in insect-proof cartons or containers, or covered with insect-proof mesh or plastic tarpaulin. These safeguards must remain intact until the lemons arrive in the United States, or the consignment will not be allowed to enter the United States.

(3) Prior to packing, the lemons must be washed, brushed, and surface disinfected for *E. australis* and *X. citri* and in accordance with the operational workplan, treated with an APHIS-approved fungicide, and waxed.

(4) After treatment, the NPPO of Argentina or officials authorized by the NPPO of Argentina must visually inspect a biometric sample of each consignment for quarantine pests, wash the lemons in this sample, and inspect the filtrate for *B. chilensis* in accordance with the operational workplan. A portion of the lemons must then be cut open and inspected for evidence of quarantine pests.

(i) If a single *C. gnidiella* or *G. aurantianum* in any stage of development is found on the lemons, the entire consignment is prohibited from export to the United States, and the registered place of production that produced the lemons is suspended from the export program until APHIS and the NPPO of Argentina jointly agree that the place of production has taken appropriate remedial measures to address plant pest risk.

(ii) If a single *B. chilensis* or *Brevipalpus* spp. mite in any stage of development is found on the lemons, the entire consignment is prohibited from export, and the registered place of production that that produced the lemons may be suspended from the export program, pending an investigation.

(iii) If a single immature Medfly is found in or with the lemons, the lemons must be treated in accordance with part 305 of this chapter and the operational workplan. Additionally, the registered place of production that produced the lemons in the consignment may be suspended from the export program, pending an investigation.

(5) If APHIS or the NPPO of Argentina determines that a registered packinghouse has failed to follow the requirements in this paragraph (c), the packinghouse will be excluded from the export program until APHIS and the NPPO of Argentina jointly agree that the packinghouse has taken appropriate remedial measures to address the plant pest risk.

(d) *Port of entry requirements.* Consignments of lemons from Argentina will be inspected at the port of entry into the United States. If any quarantine pests are discovered on the lemons during inspection, the entire lot in which the quarantine pest was discovered will be subject to appropriate remedial measures to address this risk.

Done in Washington, DC, this 4th day of May 2016.

Michael L. Gregoire,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2016–10957 Filed 5–9–16; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–6414; Directorate Identifier 2015–NM–175–AD]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc. Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain Bombardier, Inc. Model CL–600–2B19 (Regional Jet Series 100 & 440) airplanes. This proposed AD was prompted by two in-service incidents of a loss of all air data information in the flight deck. This proposed AD would require a revision of the airplane flight manual (AFM) emergency procedures section to provide procedures to guide the crew on how to stabilize the airplane airspeed and attitude for continued safe flight when a loss of all air data information has occurred in the flight deck. We are proposing this AD to prevent loss of control when a loss of all air data information has occurred in the flight deck.

DATES: We must receive comments on this proposed AD by June 24, 2016.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov*. Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–5000; fax 514–855–7401; email *thd.crj@aero.bombardier.com;* Internet *http://www.bombardier.com*. You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–6414; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Assata Dessaline, Aerospace Engineer, Avionics and Services Branch, ANE–172, FAA, New York Aircraft Certification Office (ACO), 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7301; fax 516–794–5531.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA–2016–6414; Directorate Identifier 2015–NM–175–AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued Canadian Airworthiness Directive CF–2015–12, dated June 23, 2015 (referred to after this as the Mandatory Continuing Airworthiness Information, or "the MCAI"), to correct an unsafe condition for certain Bombardier, Inc. Model CL–600–2B19 (Regional Jet Series 100 & 440) airplanes. The MCAI states:

> Two in-service incidents have been reported on CL–600–2C10 aeroplanes regarding a loss of all air data information in the cockpit. The air data information was recovered as the aeroplane descended to lower altitudes. An investigation determined that the root cause in both events was high altitude icing (ice crystal contamination). If not addressed, this condition may affect continued safe flight.
>
> Due to similarities in the air data systems, such events could happen on all Bombardier CRJ models, CL–600–2B19, CL–600–2C10, CL–600–2D15, CL–600–2D24 and CL–600–2E25. Therefore, the corrective actions for these models will be mandated once their respective Airplane Flight Manual (AFM) revisions become available.
>
> This [Canadian] AD mandates the incorporation of AFM procedures to guide the crew to stabilize the aeroplane's airspeed and attitude for continued safe flight.

You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–6414.

Related Service Information Under 1 CFR Part 51

We reviewed Section 03–19, Unreliable Airspeed, Revision 63, dated February 13, 2015, of Chapter 3, Emergency Procedures, in the Bombardier CRJ Series Regional Jet Model CL–600–2B19 Airplane Flight Manual CSP A–012, Revision 64B, dated December 8, 2015. The service information describes procedures to guide the crew to stabilize the airplane's airspeed and attitude for continued safe flight when a loss of all air data information has occurred in the flight deck. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type designs.

Costs of Compliance

We estimate that this proposed AD affects 500 airplanes of U.S. registry.

We also estimate that it would take about 1 work-hour per product to comply with the basic requirements of this proposed AD. The average labor rate is $85 per work-hour. Based on these figures, we estimate the cost of this proposed AD on U.S. operators to be $42,500, or $85 per product.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, Section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

1. Is not a "significant regulatory action" under Executive Order 12866;
2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Bombardier, Inc.: Docket No. FAA–2016–6414; Directorate Identifier 2015–NM–175–AD.

(a) Comments Due Date

We must receive comments by June 24, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Bombardier, Inc. Model CL–600–2B19 (Regional Jet Series 100 & 440) airplanes, certificated in any category, serial numbers 7003 and subsequent.

(d) Subject

Air Transport Association (ATA) of America Code 34, Navigation.

(e) Reason

This AD was prompted by two in-service incidents of a loss of all air data information in the flight deck. We are issuing this AD to prevent loss of control when a loss of all air data information has occurred in the flight deck.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Airplane Flight Manual Revision

Within 30 days after the effective date of this AD, revise the emergency procedures section of the airplane flight manual (AFM) by incorporating Section 03–19, Unreliable Airspeed, Revision 63, dated February 13, 2015, of Chapter 3, Emergency Procedures, in the Bombardier CRJ Series Regional Jet Model CL–600–2B19 Airplane Flight Manual CSP A–012, Revision 64B, dated December 8, 2015.

(h) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York Aircraft Certification Office (ACO), ANE–170, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the ACO, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; fax 516–794–5531. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, New York ACO, ANE–170, FAA; or Transport Canada Civil Aviation (TCCA); or Bombardier, Inc.'s TCCA Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(i) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) Canadian Airworthiness Directive CF–2015–12, dated June 23, 2015, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–6414.

(2) For service information identified in this AD, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–5000; fax 514–855–7401; email *thd.crj@aero.bombardier.com;* Internet *http://www.bombardier.com.* You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on April 28, 2016.

Dionne Palermo,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–10732 Filed 5–9–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–6551; Directorate Identifier 2013–SW–070–AD]

RIN 2120–AA64

Airworthiness Directives; Bell Helicopter Textron Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain Bell Helicopter Textron (Bell) Model 430 helicopters. This proposed AD would require establishing a life limit for a certain main rotor hub attachment bolt (bolt) and removing from service each bolt that has met or exceeded its life limit. This proposed AD is prompted by a documentation error that omitted the life limit of a certain part-numbered bolt from the Airworthiness Limitations section of the maintenance manual. The proposed actions are intended to establish a life limit for a certain part-numbered bolt to prevent failure of a bolt, failure of a main rotor hub, and subsequent loss of control of a helicopter.

DATES: We must receive comments on this proposed AD by July 11, 2016.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Docket:* Go to *http://www.regulations.gov.* Follow the online instructions for sending your comments electronically.
- *Fax:* 202–493–2251.
- *Mail:* Send comments to the U.S. Department of Transportation, Docket

Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.

- *Hand Delivery:* Deliver to the "Mail" address between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–6551; or in person at the Docket Operations Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the economic evaluation, any comments received, and other information. The street address for the Docket Operations Office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

For service information identified in this proposed rule, contact Bell Helicopter Textron Canada Limited, 12,800 Rue de l'Avenir, Mirabel, Quebec J7J1R4; telephone (450) 437–2862 or (800) 363–8023; fax (450) 433–0272; or at *http://www.bellcustomer.com/files/.* You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy, Room 6N–321, Fort Worth, TX 76177.

FOR FURTHER INFORMATION CONTACT: Matt Fuller, Senior Aviation Safety Engineer, Safety Management Group, Rotorcraft Directorate, FAA, 10101 Hillwood Pkwy, Fort Worth, TX 76177; telephone (817) 222–5110; email *matthew.fuller@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to participate in this rulemaking by submitting written comments, data, or views. We also invite comments relating to the economic, environmental, energy, or federalism impacts that might result from adopting the proposals in this document. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments, or if comments are filed electronically, commenters should submit only one time.

We will file in the docket all comments that we receive, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, we will consider all comments we receive on or before the closing date for comments. We will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. We may change this proposal in light of the comments we receive.

Discussion

Transport Canada, which is the aviation authority for Canada, has issued AD No. CF–2013–26, dated September 24, 2013, to correct an unsafe condition for certain serial-numbered Bell Model 430 helicopters. Transport Canada advises that bolt part number (P/N) MS21250–08083, which replaced bolt P/N 20–065–08083 in 2009, has a retirement life of 5,000 hours. However, the retirement life for the replacement bolt was inadvertently omitted from the limitations section of the Bell 430 maintenance manual. Transport Canada advises that this situation, if not corrected, could result in failure of a bolt and loss of control of the helicopter. Transport Canada AD No. CF–2013–26 requires reviewing the helicopter records to determine if bolt P/N MS21250–08083 is installed, creating a historical service record, and establishing an airworthiness life of 5,000 hours air time.

FAA's Determination

This helicopter has been approved by the aviation authority of Canada and is approved for operation in the United States. Pursuant to our bilateral agreement with Canada, Transport Canada, its technical representative, has notified us of the unsafe condition described in its AD. We are proposing this AD because we evaluated all known relevant information and determined that an unsafe condition is likely to exist or develop on other products of the same type design.

Related Service Information

We reviewed Bell Helicopter Alert Service Bulletin 430–12–47, dated November 14, 2012 (ASB). The ASB states that original bolt P/N 20–065–08083 has a retirement life of 5,000 hours but has been replaced by standard bolt P/N MS21250–08083, which does not have a life limit listed in the maintenance manual. The purpose of the ASB is to establish a life limit of 5,000 hours for the replacement bolt. Bell specifies reviewing the aircraft records back to January 2009 to determine which part-numbered bolts are installed. If a replacement bolt P/N MS21250–08083 is installed, the ASB specifies using data from aircraft records to create a historical service record for the replacement bolts and reflecting the 5,000 hours life limit. The ASB also specifies updating the Bell 430 maintenance manual.

Proposed AD Requirements

This proposed AD would require within 10 hours time-in-service (TIS), revising the Airworthiness Limitations section of the applicable maintenance manual or Instructions for Continued Airworthiness (ICA) by establishing a life limit of 5,000 hours TIS for each bolt P/N MS21250–08083. This proposed AD would also require determining the number of hours TIS for each bolt and using the helicopter's hours if the hours TIS of a bolt is unknown. This proposed AD would also require removing from service each bolt that has reached or exceeded its life limit.

Differences Between This Proposed AD and the Transport Canada AD

The proposed AD would require compliance within 10 hours TIS, while the Transport Canada AD requires compliance within 60 days.

Costs of Compliance

We estimate that this proposed AD would affect 43 helicopters of U.S. Registry. We estimate that operators may incur the following costs in order to comply with this AD. At an average labor cost of $85 per work-hour, we estimate reviewing and revising the records would require 1 work-hour for a cost of about $85 per helicopter and $3,655 for the U.S. fleet. We estimate replacing a bolt that has exceeded its life limit would require 0.5 work-hour plus $290 for a replacement bolt, for a total cost of $333 per bolt.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, Section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed, I certify this proposed regulation:

1. Is not a "significant regulatory action" under Executive Order 12866;
2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared an economic evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Bell Helicopter Textron: Docket No. FAA–2016–6551; Directorate Identifier 2013–SW–070–AD.

(a) Applicability

This AD applies to Model 430 helicopters, serial number 49001 through 49129, with a main rotor head attachment bolt (bolt) part number MS21250–08083 installed, certificated in any category.

(b) Unsafe Condition

This AD defines the unsafe condition as a bolt remaining in service beyond its fatigue life. This condition could result in failure of a bolt, failure of the main rotor hub and subsequent loss of control of a helicopter.

(c) Comments Due Date

We must receive comments by July 11, 2016.

(d) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(e) Required Actions

Within 10 hours time-in-service (TIS):

(1) Revise the Airworthiness Limitations section of the applicable maintenance manual or Instructions for Continued Airworthiness (ICA) to establish a life limit of 5,000 hours TIS for each bolt P/N MS21250–08083.

(2) Determine the number of hours TIS for each bolt and update the helicopter's historical records. If the hours TIS is unknown, calculate the number of hours TIS by counting the helicopter's hours TIS beginning January 1, 2009.

(3) Remove from service each bolt that has reached or exceeded its life limit.

(f) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Safety Management Group, FAA, may approve AMOCs for this AD. Send your proposal to: Matt Fuller, Senior Aviation Safety Engineer, Safety Management Group, Rotorcraft Directorate, FAA, 10101 Hillwood Pkwy, Fort Worth, TX 76177; telephone (817) 222–5110; email *9-ASW-FTW-AMOC-Requests@faa.gov.*

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office before operating any aircraft complying with this AD through an AMOC.

(g) Additional Information

(1) Bell Helicopter Alert Service Bulletin 430–12–47, dated November 14, 2012, which is not incorporated by reference, contains additional information about the subject of this proposed rule. For service information identified in this proposed rule, contact Bell Helicopter Textron Canada Limited, 12,800 Rue de l'Avenir, Mirabel, Quebec J7J1R4; telephone (450) 437–2862 or (800) 363–8023; fax (450) 433–0272; or at *http://www.bellcustomer.com/files/.* You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy, Room 6N–321, Fort Worth, TX 76177.

(2) The subject of this AD is addressed in Transport Canada AD No. CF–2013–26, dated September 24, 2013. You may view the Transport Canada AD on the Internet at *http://www.regulations.gov* in the AD Docket.

(h) Subject

Joint Aircraft Service Component (JASC) Code: 6220 Main Rotor Head.

Issued in Fort Worth, Texas, on April 27, 2016.

James A. Grigg,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2016–10860 Filed 5–9–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–6415; Directorate Identifier 2015–NM–178–AD]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc. Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain Bombardier, Inc. Model CL–600–2C10 (Regional Jet Series 700, 701, & 702) airplanes. This proposed AD was prompted by two in-service incidents of a loss of all air data information in the flight deck. This proposed AD would require a revision of the airplane flight manual (AFM) emergency procedures section to provide procedures to guide the crew on how to stabilize the airplane airspeed and attitude for continued safe flight when a loss of all air data information has occurred in the flight deck. We are proposing this AD to prevent loss of control when a loss of all air data information has occurred in the flight deck.

DATES: We must receive comments on this proposed AD by June 24, 2016.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–5000; fax 514–855–7401; email *thd.crj@aero.bombardier.com;* Internet *http://www.bombardier.com*. You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–6415; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Assata Dessaline, Aerospace Engineer, Avionics and Services Branch, ANE–172, FAA, New York Aircraft Certification Office (ACO), 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7301; fax 516–794–5531.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA–2016–6415; Directorate Identifier 2015–NM–178–AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued Canadian Airworthiness Directive CF–2015–20, dated July 21, 2015 (referred to after this as the Mandatory Continuing Airworthiness Information, or "the MCAI"), to correct an unsafe condition for certain Bombardier, Inc. Model CL–600–2C10 (Regional Jet Series 700, 701, & 702) airplanes. The MCAI states:

> Two in-service incidents have been reported on CL–600–2C10 aeroplanes regarding a loss of all air data information in the cockpit. The air data information was recovered as the aeroplane descended to lower altitudes. An investigation determined that the root cause in both events was high altitude icing (ice crystal contamination). If not addressed, this condition may affect continued safe flight.
>
> Due to similarities in the air data systems, such events could happen on all Bombardier CRJ models, CL–600–2B19, CL–600–2C10, CL–600–2D15, CL–600–2D24 and CL–600–2E25. Therefore, the corrective actions for these models will be mandated once their respective Airplane Flight Manual (AFM) revisions become available.
>
> This [Canadian] AD mandates the incorporation of AFM procedures to guide the crew to stabilize the aeroplane's airspeed and attitude for continued safe flight.

You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–6415.

Related Service Information Under 1 CFR Part 51

We reviewed Section 03–19, Unreliable Airspeed, Revision 15, dated March 16, 2015, of Chapter 3, Emergency Procedures, in the Bombardier CRJ Series Regional Jet Model CL–600–2C10 Airplane Flight Manual CSP B–012, Revision 16A, dated November 6, 2015. The service information describes procedures to guide the crew to stabilize the airplane's airspeed and attitude for continued safe flight when a loss of all air data information has occurred in the flight deck. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type designs.

Costs of Compliance

We estimate that this proposed AD affects 269 airplanes of U.S. registry.

We also estimate that it would take about 1 work-hour per product to comply with the basic requirements of this proposed AD. The average labor rate is $85 per work-hour. Based on these figures, we estimate the cost of this proposed AD on U.S. operators to be $22,865, or $85 per product.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, Section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

1. Is not a "significant regulatory action" under Executive Order 12866;

2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);

3. Will not affect intrastate aviation in Alaska; and

4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Bombardier, Inc.: Docket No. FAA–2016–6415; Directorate Identifier 2015–NM–178–AD.

(a) Comments Due Date

We must receive comments by June 24, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Bombardier, Inc. Model CL–600–2C10 (Regional Jet Series 700, 701, & 702) airplanes, certificated in any category, serial numbers 10002 and subsequent.

(d) Subject

Air Transport Association (ATA) of America Code 34, Navigation.

(e) Reason

This AD was prompted by two in-service incidents of a loss of all air data information in the flight deck. We are issuing this AD to prevent loss of control when a loss of all air data information has occurred in the flight deck.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Airplane Flight Manual Revision

Within 30 days after the effective date of this AD, revise the emergency procedures section of the airplane flight manual (AFM) by incorporating Section 03–19, Unreliable Airspeed, Revision 15, dated March 16, 2015, of Chapter 3, Emergency Procedures, in the Bombardier CRJ Series Regional Jet Model CL–600–2C10 Airplane Flight Manual CSP B–012, Revision 16A, dated November 6, 2015.

(h) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York Aircraft Certification Office (ACO), ANE–170, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the ACO, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; fax 516–794–5531. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, New York ACO, ANE–170, FAA; or Transport Canada Civil Aviation (TCCA); or Bombardier, Inc.'s TCCA Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(i) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) Canadian Airworthiness Directive CF–2015–20, dated July 21, 2015, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–6415.

(2) For service information identified in this AD, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–5000; fax 514–855–7401; email *thd.crj@aero.bombardier.com;* Internet *http://www.bombardier.com.* You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on April 28, 2016.

Dionne Palermo,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–10734 Filed 5–9–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–6417; Directorate Identifier 2015–NM–134–AD]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for all The Boeing Company Model DC–10–10 and DC–10–10F airplanes, Model DC–10–15 airplanes, Model DC–10–30 and DC–10–30F (KC–10A and KDC–10) airplanes, Model DC–10–40 and DC–10–40F airplanes, Model MD–10–10F and MD–10–30F airplanes, and Model MD–11 and MD–11F airplanes. This proposed AD was prompted by results from fuel system reviews conducted by the manufacturer and multiple reports of fuel pump housing electrical connector failures related to ingress of airplane fluids. This proposed AD would require replacement of the fuel pump housing electrical connector or replacement of the fuel pump housing; repetitive inspections for proper operation and corrective actions if necessary; and revising the maintenance or inspection program to incorporate new airworthiness limitations. This proposed AD would also require, for certain airplanes, a general visual inspection of the protective cap and replacement if necessary. We are proposing this AD to prevent failure of the fuel pump housing electrical connector, which could result in a potential ignition source in a fuel tank and consequent fire or explosion.

DATES: We must receive comments on this proposed AD by June 24, 2016.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For The Boeing Company service information identified in this NPRM, contact Boeing Commercial Airplanes, Attention: Data & Services Management, 3855 Lakewood Boulevard, MC D800–0019, Long Beach, CA 90846–0001; phone: 206–544–5000, extension 2; fax: 206–766–5683; Internet *https://www.myboeingfleet.com.*

For Crane Aerospace & Electronics, Hydro-Aire, Inc. service information identified in this NPRM, contact Crane Aerospace & Electronics, Hydro-Aire, Inc.: 3000 Winona Avenue, Burbank, CA

91510–7722; phone: 818–526–2500; fax: 818–526–5658; email: *CommSpares@craneaerospace.com.*

You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. Boeing Service Bulletin DC10–28–264, dated May 15, 2015; and Boeing Service Bulletin MD11–28–146, dated May 15, 2015; are also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–6417.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–6417; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Philip Kush, Aerospace Engineer, Propulsion Branch, ANM–140L, FAA, Los Angeles Aircraft Certification Office (ACO), 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5263; fax: 562–627–5210; email: *Philip.kush@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA–2016–6417; Directorate Identifier 2015–NM–134–AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

The FAA has examined the underlying safety issues involved in fuel tank explosions on several large transport airplanes, including the adequacy of existing regulations, the service history of airplanes subject to those regulations, and existing maintenance practices for fuel tank systems. As a result of those findings, we issued a regulation titled "Transport Airplane Fuel Tank System Design Review, Flammability Reduction and Maintenance and Inspection Requirements" (66 FR 23086, May 7, 2001). In addition to new airworthiness standards for transport airplanes and new maintenance requirements, this rule included Special Federal Aviation Regulation No. 88 ("SFAR 88," Amendment 21–78, and subsequent Amendments 21–82 and 21–83).

Among other actions, SFAR 88 requires certain type design (*i.e.,* type certificate (TC) and supplemental type certificate (STC)) holders to substantiate that their fuel tank systems can prevent ignition sources in the fuel tanks. This requirement applies to type design holders for large turbine-powered transport airplanes and for subsequent modifications to those airplanes. It requires them to perform design reviews and to develop design changes and maintenance procedures if their designs do not meet the new fuel tank safety standards. As explained in the preamble to the rule, we intended to adopt airworthiness directives to mandate any changes found necessary to address unsafe conditions identified as a result of these reviews.

In evaluating these design reviews, we have established four criteria intended to define the unsafe conditions associated with fuel tank systems that require corrective actions. The percentage of operating time during which fuel tanks are exposed to flammable conditions is one of these criteria. The other three criteria address the failure types under evaluation: single failures, combination of failures, and unacceptable (failure) experience. For all three failure criteria, the evaluations included consideration of previous actions taken that may mitigate the need for further action.

We have determined that the actions identified in this AD are necessary to reduce the potential of ignition sources inside fuel tanks, which, in combination with flammable fuel vapors, could result in fuel tank explosions and consequent loss of the airplane.

We have received multiple reports of fuel pump housing electrical connector failures related to ingress of airplane fluids. Currently installed fuel pump housing electrical connectors have 18 month repetitive inspection requirements related to AD 2011–11–05, Amendment 39–16704 (76 FR 31462, dated June 1, 2011) ("AD 2011–11–05"), and AD 2002–13–10, Amendment 39–12798 (67 FR 45053, dated July 8, 2002) ("AD 2002–13–10"). An improved fuel pump housing electrical connector has been developed to supersede the currently installed fuel pump housing electrical connector. Additionally, a secondary option has been developed that allows the operator to replace the fuel pump housing. In addition to the new fuel pump housing electrical connector, the use of environmentally sealed terminal lugs will help to prevent the wicking of airplane fluids into the fuel pump wires and the fuel pump housing electrical connector. This condition, if not corrected, could result in failure of the fuel pump housing electrical connector, causing a potential ignition source in a fuel tank and consequent fire or explosion.

Related Service Information Under 1 CFR Part 51

We reviewed the following service information.

- Boeing Service Bulletin DC10–28–264, dated May 15, 2015. The service information describes procedures for replacement of the fuel pump housing electrical connector with a new fuel pump housing electrical connector or replacement of the fuel pump housing. The service information also describes procedures for inspections for proper operation and corrective actions if necessary.
- Boeing Service Bulletin MD11–28–146, dated May 15, 2015. The service information describes procedures for replacement of the fuel pump housing electrical connector with a new fuel pump housing electrical connector or replacement of the fuel pump housing. The service information also describes procedures for inspections for proper operation and corrective actions if necessary.
- Crane Aerospace & Electronics, Hydro-Aire, Inc. Service Bulletin 60–843/845–28–2, dated October 1, 2014. The service information describes procedures for a general visual inspection of the protective cap and replacement if necessary.
- Appendixes B, C, and D of Boeing Trijet Special Compliance Item Report MDC–02K1003, Revision O, dated April 15, 2015, which include Critical Design Configuration Control Limitations (CDCCLs), Airworthiness Limitation Instructions (ALIs), and short-term extensions.

This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Other Relevant Rulemaking

AD 2000–22–21, Amendment 39–11969 (65 FR 69658, dated November 20, 2000) ("AD 2000–22–21"), applies to all The Boeing Company Model DC–10, Model MD–10, and Model MD–11 series airplanes. AD 2000–22–21 requires revising the Airplane Flight Manual (AFM) to ensure that the flight crew is advised of appropriate procedures for disabling certain fuel pump electrical circuits following failure of a fuel pump electrical connector. For certain airplanes, AD 2000–22–21 also requires revising the AFM to prohibit resetting of tripped fuel pump circuit breakers. AD 2000–22–21 was prompted by reports of four incidents on McDonnell Douglas Model DC–10 and MD–11 series airplanes, in which a short circuit occurred in the electrical connector between the power lead and the housing of a fuel pump. The circuit breaker did not trip in any of these incidents because the electrical arcing that occurred was shorter in duration than necessary for the circuit breaker to detect the arcing and open the circuit. We issued AD 2000–22–21 to prevent continued arcing following a short circuit of the fuel pump electrical connector, which could damage the conduit that protects the power lead inside the fuel tank, and result in the creation of a potential ignition source in the fuel tank.

AD 2002–13–10 applies to certain The Boeing Company Model DC–10–10, –10F, –15, –30, –30F, –30F (KC–10A and KDC–10), –40, and –40F airplanes; Model MD–10–10F and –30F airplanes; and Model MD–11 and –11F airplanes. AD 2002–13–10 requires repetitive tests for electrical continuity and resistance and repetitive inspections to detect discrepancies of the fuel boost/transfer pump connectors; and corrective actions, if necessary. AD 2002–13–10 was prompted by reports of five instances of failed connectors in the fuel boost/transfer pump circuit on The Boeing Company Model DC–10 and MD–11 series airplanes. We issued AD 2002–13–10 to prevent arcing of connectors in the fuel boost/transfer pump circuit, which could result in a fire or explosion of the fuel tank.

AD 2003–07–14, Amendment 39–13110 (68 FR 17544, dated April 10, 2003), applies to a single The Boeing Company Model DC–10–30 airplane. AD 2003–07–14 requires repetitive tests for electrical continuity and resistance and repetitive inspections to detect discrepancies of the fuel boost/transfer pump connectors; and corrective actions, if necessary. AD 2003–07–14 was prompted by reports of five instances of failed connectors in the fuel boost/transfer pump circuit on certain McDonnell Douglas Model DC–10 and MD–11 series airplanes. We issued AD 2003–07–14 to prevent arcing of connectors in the fuel boost/transfer pump circuit, which could result in a fire or explosion of the fuel tank.

AD 2008–06–21 R1, Amendment 39–16100 (74 FR 61504, November 25, 2009), applies to all McDonnell Douglas Corporation Model DC–10–10 and DC–10–10F airplanes, Model DC–10–15 airplanes, Model DC–10–30 and DC–10–30F (KC–10A and KDC–10) airplanes, Model DC–10–40 and DC–10–40F airplanes, Model MD–10–10F and MD–10–30F airplanes, and Model MD–11 and MD–11F airplanes. AD 2008–06–21 R1 requires revising the FAA-approved maintenance program, or the Airworthiness Limitations (AWLs) section of the Instructions for Continued Airworthiness, as applicable, to incorporate new AWLs for fuel tank systems to satisfy Special Federal Aviation Regulation No. 88 requirements. For certain airplanes, AD 2008–06–21 R1 also requires the initial accomplishment of a certain repetitive AWL inspection to phase in that inspection, and repair if necessary. AD 2008–06–21 R1 clarifies the intended effect of the AD on spare and on-airplane fuel tank system components. AD 2008–06–21 R1 was prompted by a design review of the fuel tank system. We issued AD 2008–06–21 R1 to prevent the potential for ignition sources inside fuel tanks caused by latent failures, alterations, repairs, or maintenance actions, which, in combination with flammable fuel vapors, could result in a fuel tank explosion and consequent loss of the airplane.

AD 2011–11–05 applies to all The Boeing Company Model DC–10–10, DC–10–10F, DC–10–15, DC–10–30, DC–10–30F (KC–10A and KDC–10), DC–10–40, DC–10–40F; Model MD–10–10F, MD–10–30F, MD–11, and MD–11F airplanes. AD 2011–11–05 requires replacing the fuel pump housing electrical connector assembly with a new part and doing repetitive inspections for continuity, resistance, and insulation resistance, and doing corrective actions if necessary. AD 2011–11–05 was prompted by reports of failures of a certain fuel pump housing electrical connector. We issued AD 2011–11–05 to detect and correct insulation resistance degradation and arcing in the potted backside of the electrical connector assembly of the fuel boost/transfer pump housing, which could compromise its performance and cause an ignition source in the fuel tank, resulting in a fuel tank explosion and consequent loss of the airplane.

FAA's Determination

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of these same type designs.

Proposed AD Requirements

This proposed AD would require replacement of the fuel pump housing electrical connector or replacement of the fuel pump housing. This proposed AD would also require, for certain airplanes, a general visual inspection of the protective cap and replacement if necessary. This proposed AD would also require repetitive inspections for proper operation of the fuel pump and corrective actions if necessary. This proposed AD would also require revising the maintenance or inspection program to incorporate new airworthiness limitations.

This proposed AD requires revisions to certain operator maintenance documents to include new actions (*e.g.*, inspections) and CDCCLs. Compliance with these actions and CDCCLs is required by 14 CFR 91.403(c). For airplanes that have been previously modified, altered, or repaired in the areas addressed by this AD, the operator may not be able to accomplish the actions described in the revisions. In this situation, to comply with 14 CFR 91.403(c), the operator must request approval for an alternative method of compliance according to paragraph (l) of this AD. The request should include a description of changes to the required inspections that will ensure the continued operational safety of the airplane.

Notwithstanding any other maintenance or operational requirements, components that have been identified as airworthy or installed on the affected airplanes before accomplishing the revision of the airplane maintenance or inspection program specified in this proposed AD, do not need to be reworked in accordance with the CDCCLs. However, once the airplane maintenance or inspection program has been revised as required by this proposed AD, future maintenance actions on these components must be done in accordance with the CDCCLs.

The phrase "corrective actions" is used in this proposed AD. "Corrective actions" correct or address any condition found. Corrective actions in an AD could include, for example, repairs.

Costs of Compliance

We estimate that this proposed AD affects 246 airplanes of U.S. registry.

We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Option 1: Replace connectors (including inspection) (122 Model DC–10, and MD–10 airplanes.).	68 work-hours × $85 per hour = $5,780.	$54,842	$60,622	$7,395,884.
Option 1: Replace connectors (including inspection) (124 Model MD–11 airplanes.).	59 work-hours × $85 per hour = $5,015.	$67,031	$72,046	$8,933,704.
Option 2: Replace fuel pump housings (122 Model DC–10, and MD–10 airplanes.).	Up to 81 work-hours × $85 per hour = $6,885.	Up to $54,842	Up to $61,727	Up to $7,530,694.
Option 2: Replace fuel pump housings (124 Model MD–11 airplanes.).	77 work-hours × $85 per hour = $6,545.	$67,031	$73,576	$9,123,424.
Maintenance or inspection program revision	1 work-hour × $85 per hour = $85.	$0	$85	$20,910.
Inspection for proper operation	Up to 130 work-hours × $85 per hour = $11,050.	$0	Up to $11,050	Up to $2,718,300.

We have received no definitive data that would enable us to provide cost estimates for the on-condition replacement and corrective actions specified in this proposed AD.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

(1) Is not a "significant regulatory action" under Executive Order 12866,

(2) Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

The Boeing Company: Docket No. FAA–2016–6417; Directorate Identifier 2015–NM–134–AD.

(a) Comments Due Date

We must receive comments by June 24, 2016.

(b) Affected ADs

This AD affects AD 2000–22–21, Amendment 39–11969 (65 FR 69658, dated November 20, 2000); AD 2002–13–10, Amendment 39–12798 (67 FR 45053, dated July 8, 2002); AD 2003–07–14, Amendment 39–13110 (68 FR 17544, dated April 10, 2003); AD 2008–06–21 R1, Amendment 39–16100 (74 FR 61504, November 25, 2009); and AD 2011–11–05, Amendment 39–16704 (76 FR 31462, dated June 1, 2011).

(c) Applicability

This AD applies to all The Boeing Company Model DC–10–10 and DC–10–10F airplanes, Model DC–10–15 airplanes, Model DC–10–30 and DC–10–30F (KC–10A and KDC–10) airplanes, Model DC–10–40 and DC–10–40F airplanes, Model MD–10–10F and MD–10–30F airplanes, and Model MD–11 and MD–11F airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 28, Fuel.

(e) Unsafe Condition

This AD was prompted by multiple reports of fuel pump housing electrical connector failures related to ingress of airplane fluids. We are issuing this AD to prevent failure of the fuel pump housing electrical connector, which could result in a potential ignition source in a fuel tank and consequent fire or explosion.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Replacement

Within 36 months after the effective date of this AD, do the actions required by paragraph (g)(1) or (g)(2) of this AD.

(1) Do a replacement of the fuel pump housing electrical connector with a new fuel pump housing electrical connector, including doing a general visual inspection of the protective cap for a spring and applicable replacement of the protective cap, in accordance with the Accomplishment Instructions of Boeing Service Bulletin DC10–28–264, dated May 15, 2015; or Boeing Service Bulletin MD11–28–145, dated May 15, 2015, as applicable; and Crane Aerospace & Electronics, Hydro-Aire, Inc. Service Bulletin 60–843/845–28–2, dated October 1, 2014.

(2) Do a replacement of the fuel boost pump housing with a new fuel boost pump housing, in accordance with the Accomplishment Instructions of Boeing Service Bulletin DC10–28–264, dated May 15, 2015; or Boeing Service Bulletin MD11–28–146, dated May 15, 2015, as applicable.

(h) Repetitive Inspections

Within 24 months after accomplishing the replacement required by paragraph (g) of this AD, do an inspection for proper operation of the fuel pump and all applicable corrective actions, in accordance with Appendix A, "24 Month Repetitive Inspection," of Boeing Service Bulletin DC10–28–264, dated May 15, 2015; or Boeing Service Bulletin MD11–28–146, dated May 15, 2015; as applicable. Do all applicable corrective actions before further flight. Repeat the inspection thereafter at intervals not to exceed 24 months.

(i) Maintenance or Inspection Program Revision

Within 30 days after accomplishing the replacement required by paragraph (g) of this AD, or within 30 days after the effective date of this AD, whichever occurs later, revise the maintenance or inspection program, as applicable, to incorporate the Critical Design Configuration Control Limitations (CDCCLs), Airworthiness Limitation Instructions (ALIs), and short-term extensions specified in Appendices B, C, and D of Boeing Trijet Special Compliance Item (SCI) Report MDC–02K1003, Revision O, dated April 15, 2015. The initial compliance time for accomplishing the actions specified in the ALIs is at the later of the times specified in paragraphs (i)(1) and (i)(2) of this AD. Revising the maintenance or inspection program required by this paragraph terminates the requirements in paragraphs (g) and (h) of AD 2008–06–21 R1, Amendment 39–16100 (74 FR 61504, November 25, 2009).

(1) At the applicable time specified in Appendix C of Boeing Trijet SCI Report MDC–02K1003, Revision O, dated April 15, 2015, except as provided by Appendix D of Boeing Trijet SCI Report MDC–02K1003, Revision O, dated April 15, 2015.

(2) Within 30 days after accomplishing the actions required by paragraph (g) of this AD, or within 30 days after the effective date of this AD, whichever occurs later.

(j) No Alternative Actions, Intervals, or CDCCLs

After the maintenance or inspection program has been revised as required by paragraph (i) of this AD, no alternative actions (*e.g.*, inspections), intervals, or CDCCLs may be used unless the actions, intervals, or CDCCLs are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in paragraph (l) of this AD.

(k) Terminating Action for Certain Paragraphs of Other ADs

Accomplishing the actions required by paragraph (g) of this AD terminates the requirements specified in paragraphs (k)(1), (k)(2), (k)(3), and (k)(4) of this AD for that airplane only.

(1) The actions required by paragraph (a) of AD 2000–22–21, Amendment 39–11969 (65 FR 69658, dated November 20, 2000).

(2) The actions required by paragraphs (a) and (b) of AD 2002–13–10, Amendment 39–12798 (67 FR 45053, dated July 8, 2002).

(3) The actions required by paragraphs (a) and (b) of AD 2003–07–14, Amendment 39–13110 (68 FR 17544, dated April 10, 2003).

(4) The actions required by paragraph (j) of AD 2011–11–05, Amendment 39–16704 (76 FR 31462, dated June 1, 2011).

(l) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Los Angeles Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in paragraph (m)(1) of this AD. Information may be emailed to: *9-ANM-LAACO-AMOC-Requests@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Los Angeles ACO to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(4) For service information that contains steps that are labeled as Required for Compliance (RC), the provisions of paragraphs (l)(4)(i) and (l)(4)(ii) of this AD apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

(ii) Steps not labeled as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

(m) Related Information

(1) For more information about this AD, contact Philip Kush, Aerospace Engineer, Propulsion Branch, ANM–140L, FAA, Los Angeles Aircraft Certification Office (ACO), 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5263; fax: 562–627–5210; email: *Philip.kush@faa.gov.*

(2) For The Boeing Company service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, 3855 Lakewood Boulevard, MC D800–0019, Long Beach, CA 90846–0001; phone: 206–544–5000, extension 2; fax: 206–766–5683; Internet *https://www.myboeingfleet.com.*

(3) For Crane Aerospace & Electronics, Hydro-Aire, Inc. service information identified in this AD, contact Crane Aerospace & Electronics, Hydro-Aire, Inc.: 3000 Winona Avenue, Burbank, CA 91510–7722; phone: 818–526–2500; fax: 818–526–5658; email: *CommSpares@craneaerospace.com.*

(4) You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, WA, on April 27, 2016.

Dionne Palermo,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–10735 Filed 5–9–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–6426; Directorate Identifier 2016–NM–023–AD]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for all The Boeing Company Model 737–300, -400, and -500 series airplanes. This proposed AD was prompted by reports of intergranular cracks on the front spar chord lugs of the outboard horizontal stabilizer. This proposed AD would require repetitive inspections of the front spar chord lugs and lug bores of the horizontal stabilizer, and repair if

necessary. We are proposing this AD to detect and correct cracking of the front spar chord lugs of the horizontal stabilizer. Such cracking could cause stabilizer instability, adversely affect controllability of the airplane, and adversely affect the structural integrity of the airplane.

DATES: We must receive comments on this proposed AD by June 24, 2016.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- Federal eRulemaking Portal: Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–6426.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–6426; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Gaetano Settineri, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6577; fax: 425–917–6590; email: *gaetano.settineri@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include “Docket No. FAA–2016–6426; Directorate Identifier 2016–NM–023–AD” at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

We have received reports of intergranular cracks on the front spar chord lugs of the outboard horizontal stabilizer. The cracks have been found along the axis of the front spar chord and in the lug faces, lug bores, and lug spot-face surfaces. The stabilizer front spar chords are an extrusion made from 7075–T6511 aluminum. This material is susceptible to stress corrosion in a corrosive environment where residual machining stresses are present and where the material finish and sealant have degraded. A single joint failure will significantly reduce the remaining fatigue life in the rear spar. A dual failure of the upper and lower front spar joints of the horizontal stabilizer could cause stabilizer instability, adversely affect controllability of the airplane, and adversely affect the structural integrity of the airplane.

Related Service Information Under 1 CFR Part 51

We reviewed Boeing Alert Service Bulletin 737–55A1092, dated August 7, 2015. The service information describes procedures for doing inspections for corrosion and cracking of the front spar chord lugs of the horizontal stabilizer, and inspections for corrosion of the lug bores. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA’s Determination

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

This proposed AD would require accomplishing the actions specified in the service information described previously, except as discussed under “Differences Between this Proposed AD and the Service Information. For information on the procedures and compliance times, see this service information at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–6426.

Differences Between This Proposed AD and the Service Information

Boeing Alert Service Bulletin 737–55A1092, dated August 7, 2015, specifies to contact the manufacturer for instructions on how to repair certain conditions, but this AD would require repairing those conditions in one of the following ways:

- In accordance with a method that we approve; or
- Using data that meet the certification basis of the airplane, and that have been approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) whom we have authorized to make those findings.

Costs of Compliance

We estimate that this proposed AD affects 346 airplanes of U.S. registry. We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspections	14 work-hours × $85 per hour = $1,190 per inspection cycle.	$0	$1,190 per inspection cycle.	$411,740 per inspection cycle

We have received no definitive data that would enable us to provide cost estimates for the on-condition actions specified in this proposed AD.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

(1) Is not a "significant regulatory action" under Executive Order 12866,

(2) Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

The Boeing Company: Docket No. FAA–2016–6426; Directorate Identifier 2016–NM–023–AD.

(a) Comments Due Date

We must receive comments by June 14, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all The Boeing Company Model 737–300, –400, and –500 series airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 55, Stabilizers.

(e) Unsafe Condition

This AD was prompted by reports of intergranular cracks on the front spar chord lugs of the outboard horizontal stabilizer. We are issuing this AD to detect and correct cracking of the front spar chord lugs of the horizontal stabilizer. Such cracking could cause stabilizer instability, adversely affect controllability of the airplane, and adversely affect the structural integrity of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Repetitive Inspections and Repairs

Within 27 months after the effective date of this AD: Do the actions required by paragraphs (g)(1) and (g)(2) of this AD, and do all applicable repairs, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 737–55A1092, dated August 7, 2015, except as required by paragraph (h) of this AD. Do all applicable repairs before further flight. Repeat the inspections specified in paragraphs (g)(1) and (g)(2) of this AD thereafter at the applicable intervals specified in paragraph 1.E., "Compliance," of Boeing Alert Service Bulletin 737–55A1092, dated August 7, 2015.

(1) Do a detailed inspection for corrosion and an ultrasonic inspection for cracking of the front spar chord lugs of the left and right horizontal stabilizers.

(2) Do a detailed inspection for corrosion of the lug bores of the front spar chord of the left and right horizontal stabilizers.

(h) Service Information Exception

Where Boeing Alert Service Bulletin 737–55A1092, dated August 7, 2015, specifies to contact Boeing for appropriate action, and specifies that action as "RC" (Required for Compliance): Before further flight, repair using a method approved in accordance with the procedures specified in paragraph (j) of this AD.

(i) Parts Installation Limitation

As of the effective date of this AD: No person may install a replacement horizontal stabilizer on any airplane, unless the actions required by paragraphs (g)(1) and (g)(2) of this AD, and all applicable repairs are done prior to installation in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 737–55A1092, dated August 7, 2015, except as required by paragraph (h) of this AD. Repeat the inspections specified in paragraph (g)(1) and (g)(2) of this AD thereafter at the applicable intervals specified in paragraph 1.E., "Compliance," of Boeing Alert Service Bulletin 737–55A1092, dated August 7, 2015.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in paragraph (k)(1) of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet

the certification basis of the airplane, and the approval must specifically refer to this AD.

(4) Except as required by paragraph (h) of this AD: For service information that contains steps that are labeled as RC, the provisions of paragraphs (j)(4)(i) and (j)(4)(ii) of this AD apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

(ii) Steps not labeled as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

(k) Related Information

(1) For more information about this AD, contact Gaetano Settineri, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6577; fax: 425–917–6590; email: *gaetano.settineri@faa.gov.*

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com.* You may view this referenced service information at the FAA, the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on April 28, 2016.

Dionne Palermo,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–10634 Filed 5–9–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–5872; Directorate Identifier 2016–NE–11–AD]

RIN 2120–AA64

Airworthiness Directives; General Electric Company Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for all General Electric Company (GE) GEnx-1B64/P2, -1B67/P2, -1B70/P2, -1B70C/P2, -1B70/75/P2, and -1B74/75/P2 turbofan engines with engine assembly, part number (P/N) 2447M10G01 or P/N 2447M10G02, installed. This proposed AD was prompted by a report of a significant fan rub event. This proposed AD would require rework of the engine fan stator module assembly. We are proposing this AD to prevent failure of the fan blades and the load reduction device, loss of power to one or more engines, loss of thrust control, and loss of the airplane.

DATES: We must receive comments on this proposed AD by July 11, 2016.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact General Electric Company, GE Aviation, Room 285, 1 Neumann Way, Cincinnati, OH 45215; phone: 513–552–3272; email: *aviation.fleetsupport@ge.com.* You may view this service information at the FAA, Engine & Propeller Directorate, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call 781–238–7125.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–5872; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Christopher McGuire, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–7120; fax: 781–238–7199; email: *chris.mcguire@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this NPRM. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA–2016–5872; Directorate Identifier 2016–NE–11–AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this NPRM. We will consider all comments received by the closing date and may amend this NPRM because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this NPRM.

Discussion

We received a report of a significant fan rub event involving a GE GEnx-1B Performance Improvement Program 2 (PIP2) engine. The fan rub was caused by partial fan ice shedding. Asymmetric ice shedding can cause large fan imbalances leading to heavy tip rubs. The fan case geometry on PIP2 engines makes these engines susceptible to heavy fan tip rubs. This can cause substantial damage to the engine and an in-flight non-restartable power loss. We are using calendar time for compliance in this AD because the failure mode is caused by exposure to specific environmental and operational conditions. This defines the overall fleet risk in terms of calendar time, rather than engine cycles or hours.

This condition, if not corrected, could result in failure of the fan blades and the load reduction device, loss of power to one or more engines, loss of thrust control, and loss of the airplane.

Related Service Information Under 1 CFR Part 51

We reviewed GE GEnx–1B Service Bulletin (SB) 72–0314 R00, dated April 1, 2016. The SB describes procedures for increasing the clearance of the fan stator module assembly. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

We are proposing this NPRM because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

This NPRM would require accomplishing the actions specified in the service information described previously.

Costs of Compliance

We estimate that this proposed AD will affect 89 engines installed on airplanes of U.S. registry. We also estimate that it will take about 40 hours per engine to comply with this proposed AD. The average labor rate is $85 per hour. Based on these figures, we estimate the total cost of this proposed AD to U.S. operators to be $302,600.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

(1) Is not a "significant regulatory action" under Executive Order 12866,

(2) Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

General Electric Company: Docket No. FAA–2016–5872; Directorate Identifier 2016–NE–11–AD.

(a) Comments Due Date

We must receive comments by July 11, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all General Electric Company (GE) GEnx–1B64/P2, –1B67/P2, –1B70/P2, –1B70C/P2, –1B70/75/P2, and –1B74/75/P2 turbofan engines with engine assembly, part number (P/N) 2447M10G01 or P/N 2447M10G02, installed.

(d) Unsafe Condition

This AD was prompted by a report of a significant fan rub event. We are issuing this AD to prevent failure of the fan blades and the load reduction device, loss of power to one or more engines, loss of thrust control, and loss of the airplane.

(e) Compliance

Comply with this AD within the compliance times specified, unless already done.

(1) Modify the fan stator module assembly before December 31, 2016.

(2) Use paragraphs 3.B.(1) through 3.B.(6) or 3.C.(1) through 3.C.(6) of the Accomplishment Instructions of GE GEnx–1B Service Bulletin (SB) 72–0314 R00, dated April 1, 2016, to do the modification.

(f) Credit for Previous Action

You may take credit for the fan stator module assembly modification that is required by paragraph (e) of this AD if you performed the modification before the effective date of this AD using the Accomplishment Instructions, paragraphs 3.B. or 3.C., of GE GEnx–1B SB 72–0309 R00, dated March 11, 2016.

(g) Alternative Methods of Compliance (AMOCs)

The Manager, Engine Certification Office, FAA, may approve AMOCs to this AD. Use the procedures found in 14 CFR 39.19 to make your request. You may email your request to: *ANE-AD-AMOC@faa.gov.*

(h) Related Information

(1) For more information about this AD, contact Christopher McGuire, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–7120; fax: 781–238–7199; email: *chris.mcguire@faa.gov.*

(2) AD 2016–06–08 (81 FR 14704, March 18, 2016) and AD 2016–08–12 (81 FR 23581, April 22, 2016) pertain to the subject of this proposed AD.

(3) GE GEnx–1B SB 72–0314 R00, dated April 1, 2016 can be obtained from GE using the contact information in paragraph (h)(4) of this proposed AD.

(4) For service information identified in this proposed AD, contact General Electric Company, GE Aviation, Room 285, 1 Neumann Way, Cincinnati, OH 45215; phone: 513–552–3272; email: *aviation.fleetsupport@ge.com.*

(5) You may view this service information at the FAA, Engine & Propeller Directorate, 1200 District Avenue, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

Issued in Burlington, Massachusetts, on May 3, 2016.

Colleen M. D'Alessandro,

Manager, Engine & Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2016–10781 Filed 5–9–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1100, 1140, and 1143

[Docket No. FDA–2015–D–2325]

Tobacco Product Master Files; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Tobacco Product Master Files." This guidance provides recommendations to industry on tobacco product master files (TPMFs). TPMFs are voluntary submissions used to permit the person that owns the TPMF to authorize other parties to rely on information in the TPMF to support a submission to FDA without the TPMF owner having to disclose that

information to the authorized parties. Parties that obtain a right of reference from a TPMF owner may reference information in a TPMF that the TPMF owner does not want to make public, but that the other party would otherwise need to develop on its own to make a complete submission to FDA.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2015–D–2325 for "Tobacco Product Master Files; Guidance for Industry." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION". The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA"s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of this guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–2000. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Annette Marthaler or Nathan Mease, Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–2000, 1–877–287–1373, email: *AskCTP@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Tobacco Product Master Files." This guidance is being issued consistent with FDA's good guidance practices (GGP) regulation (§ 10.115 (21 CFR 10.115)). This guidance is being implemented without prior public comment because the Agency has determined that prior public participation is not feasible or appropriate (§ 10.115(g)(2)). The Agency made this determination because immediate implementation of the guidance is needed to assist in addressing a public health issue. Although this guidance document is immediately in effect, it remains subject to comment in accordance with the Agency's GGP regulation.

The guidance document provides recommendations to industry on TPMFs. TPMFs are voluntary submissions to FDA that contain information about a tobacco product. TPMFs are used to permit the person who owns the TPMF (TPMF owner) to authorize other persons to rely on information in the TPMF to support a submission to FDA without the TPMF owner having to disclose that information to other persons. Authorization to reference a TPMF may be especially useful to manufacturers or applicants preparing premarket submissions, such as substantial equivalence reports, for new tobacco products. Other parties who obtain a right of reference from a TPMF owner can reference information in a TPMF that the TPMF owner does not want to make public, but that the other party would otherwise need to develop on its own to make a complete submission to FDA. The guidance provides information on how to establish a TPMF, including what to submit and where to submit the TPMF.

The guidance represents the current thinking of FDA on TPMFs. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to collections of information described in FDA's final rule on Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products. The collections of information in the final rule are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). As required by the PRA, FDA has published an analysis of the information collection provisions elsewhere in this issue of the **Federal Register** and has submitted them for OMB approval.

This guidance also refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the PRA (44 U.S.C. 3501–3520). The collections of information in section 905(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) have been approved under OMB control number 0910–0673; the collections of information in sections 904(a)(1), (c) and 905(b), (c), (d), (h), (i) of the FD&C Act have been approved under OMB control number 0910–0650; the collections of information in section 904(a)(4) of the FD&C Act have been approved under OMB control number 0910–0654; the collections of information in 21 CFR 1107.1(b) and (c), 21 CFR 25.40, and section 905(j)(1)(A)(ii) of the FD&C Act have been approved under OMB control number 0910–0684; the collections of information in sections 904(a)(3) and 904(c)(1) of the FD&C Act have been approved under OMB control number 0910–0732; and the collections of information in section 910 have been approved under OMB control number 0910–0775.

III. Electronic Access

Persons with access to the Internet may obtain an electronic version of the guidance at either *http://www.regulations.gov* or *http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm.*

Dated: May 3, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–10690 Filed 5–5–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1100, 1140, and 1143

[Docket No. FDA–2014–N–0189]

The Food and Drug Administration Deems Certain Tobacco Products Subject to FDA Authority, Sales and Distribution Restrictions, and Health Warning Requirements for Packages and Advertisements; Small Entity Compliance Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "FDA Deems Certain Tobacco Products Subject to FDA Authority, Sales and Distribution Restrictions, and Health Warning Requirements for Packages and Advertisements; Small Entity Compliance Guide." This small entity compliance guide (SECG) is intended to set forth in plain language the requirements of the deeming regulation and to help small businesses understand and comply with the regulation.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2014–N–0189 for "FDA Deems Certain Tobacco Products Subject to FDA Authority, Sales and Distribution Restrictions, and Health Warning Requirements for Packages and Advertisements; Small Entity Compliance Guide." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION". The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of this guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Katherine Collins, Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–2000, 1–877–287–1373, email: *AskCTP@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "FDA Deems Certain Tobacco Products Subject to FDA Authority, Sales and Distribution Restrictions, and Health Warning Requirements for Packages and Advertisements, Small Entity Compliance Guide." This guidance is intended to help small businesses understand and comply with FDA's implementation of the final rule entitled "Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products" (Deeming rule), which is published elsewhere in this edition of the **Federal Register**. Specifically, this guidance is intended to help small businesses understand how to comply with FDA's final rule deeming tobacco products to be subject to the Federal Food, Drug, and Cosmetic Act ("FD&C Act"), as amended by the Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act"). The Deeming rule extends FDA's authority in Chapter IX of the FD&C Act to include all tobacco products, except accessories of newly deemed tobacco products. The Deeming rule also prohibits the sale of covered tobacco products to individuals under the age of 18, prohibits vending machine sales unless sold in adult-only facilities, and requires the display of health warning statements on cigarette tobacco, roll-your-own tobacco, and covered tobacco product packages and in advertisements.

In compliance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104–121), FDA is making available this SECG stating in plain language the legal requirements of the Deeming final rule, set forth in 21 CFR parts 1100, 1140, and 1143.

II. Significance of Guidance

FDA is issuing this SECG as a level 2 guidance, consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public unless specific regulatory or statutory requirements are cited. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons with access to the Internet may obtain an electronic version of the guidance at either *http://www.regulations.gov* or *http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm.*

Dated: May 3, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–10684 Filed 5–5–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1100, 1140, and 1143

[Docket No. FDA–2015–D–2496]

Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems; Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems." Given the relatively new presence of electronic nicotine delivery systems (ENDS) on the U.S. market and FDA's final rule deeming these products to be subject to the tobacco product authorities in the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA expects to receive premarket tobacco product application (PMTA) submissions from manufacturers of ENDS. This draft guidance is intended to assist persons with their PMTA submissions for ENDS products.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by July 11, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov*.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2015–D–2496 for "Premarket Tobacco Product Application for Electronic Nicotine Delivery Systems." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov*. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of this draft guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–2000. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the draft guidance may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: *With regard to the draft guidance:* Colleen Lee, Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–2000, 1–877–287–1373, *AskCTP@fda.hhs.gov*.

With regard to the proposed collection of information: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems."

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and granted FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health generally and to reduce tobacco use by minors. Under section 901(b) of the FD&C Act (21 U.S.C. 387a(b)), FDA's tobacco product authorities in chapter IX of the FD&C Act apply to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary of Health and Human Services by regulation deems to be subject to chapter IX. Concurrently with issuing this draft guidance, FDA is publishing elsewhere in this issue of the **Federal Register**, its final rule, "Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products" (Deeming rule) to deem all products meeting the statutory definition of "tobacco product" in section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)), except accessories to newly deemed tobacco products, to be subject to chapter IX of the FD&C Act (21 U.S.C. 387 through 387u).

Under section 910 of the FD&C Act (21 U.S.C. 387j), persons seeking to market a new tobacco product (as defined in section 910(a)(1) of the FD&C Act) must first submit a PMTA to FDA and obtain a marketing authorization order, unless FDA has issued an order that the new tobacco product is substantially equivalent to a tobacco product commercially marketed in the United States as of February 15, 2007, or the new tobacco product is exempt from demonstrating substantial equivalence pursuant to the reasons outlined in section 905(j)(3) of the FD&C Act (21 U.S.C. 387e(j)(3)). The ENDS products that are the subject of this draft guidance likely would be considered new tobacco products.

Given the relatively new presence of ENDS on the U.S. market, FDA anticipates that many manufacturers of these new tobacco products will seek a marketing authorization order by filing a PMTA. This draft guidance explains, among other things, products to which the guidance applies, when a PMTA is required, general procedures for review of an ENDS PMTA, what information the FD&C Act requires applicants to submit in a PMTA, and what information FDA recommends applicants submit in an ENDS PMTA to show whether permitting such new tobacco product to be marketed is appropriate for the protection of the public health.

II. Significance of Draft Guidance

FDA is issuing this draft guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on PMTAs for ENDS. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

This draft guidance refers to collections of information described in FDA's Deeming rule, which this draft guidance is intended to interpret. The collections of information in the Deeming rule are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). As required by the PRA, FDA has published an analysis of the information collection provisions elsewhere in this issue of the **Federal Register** and has submitted them for OMB approval.

IV. Electronic Access

Persons with access to the Internet may obtain an electronic version of the draft guidance at either *http://www.regulations.gov* or *http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm.*

Dated: May 3, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–10687 Filed 5–5–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1150

[Docket No. FDA–2014–D–0917]

Requirements for the Submission of Data Needed To Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products; Small Entity Compliance Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised guidance for industry entitled "Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products; Small Entity Compliance Guide" for the final user fees rule published July 10, 2014, and for the new user fees regulation. This revised guidance, a small entity compliance guide (SECG), replaces the SECG of the same name published on July 16, 2014. The revised SECG is intended to set forth in plain language the requirements of the user fee regulations and to help small businesses understand and comply with the regulations.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2014–D–0917 for "Small Entity Compliance Guide: Requirements for the Submission of Data Needed To Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of this guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent. See the

SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Paul Hart, Center for Tobacco Products, Food and Drug Administration, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993, 1–877–287–1373, email: *AskCTP@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised guidance for industry entitled "Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products; Small Entity Compliance Guide" for the final user fee rules published July 10, 2014 (79 FR 39302). Also, published elsewhere in this edition of the **Federal Register**, FDA issued a final rule to amend 21 CFR part 1150 (part 1150) to require domestic manufacturers and importers of cigars and pipe tobacco to submit to FDA information needed to calculate the amount of user fees assessed under the Federal Food, Drug, and Cosmetic Act (FD&C Act). FDA issued this user fee final rule together with the final rule, "Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products" (Deeming rule), which deems all products that meet the statutory definition of "tobacco product," except accessories of the newly deemed tobacco products, to be subject to the FD&C Act. The Deeming rule, among other things, subjects domestic manufacturers and importers of cigars and pipe tobacco to the FD&C Act's user fee requirements. Consistent with the Deeming rule and the requirements of the FD&C Act, this user fee final rule requires the submission of the information needed to calculate user fee assessments for each manufacturer and importer of cigars and pipe tobacco to FDA. In compliance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104–121), FDA is making available this revised SECG stating in plain language the legal requirements of the user fee final regulations set forth in part 1150.

II. Significance of Guidance

FDA is issuing this revised SECG as a level 2 guidance, consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public unless specific regulatory or statutory requirements are cited. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons with access to the Internet may obtain an electronic version of the guidance at either *http://www.regulations.gov* or *http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm.*

Dated: May 3, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–10689 Filed 5–5–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 301

[REG–127199–15]

RIN 1545–BM94

Treatment of Certain Domestic Entities Disregarded as Separate From Their Owners as Corporations for Purposes of Section 6038A

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations that would treat a domestic disregarded entity wholly owned by a foreign person as a domestic corporation separate from its owner for the limited purposes of the reporting, record maintenance and associated compliance requirements that apply to 25 percent foreign-owned domestic corporations under section 6038A of the Internal Revenue Code. These changes are intended to provide the IRS with improved access to information that it needs to satisfy its obligations under U.S. tax treaties, tax information exchange agreements and similar international agreements, as well as to strengthen the enforcement of U.S. tax laws.

DATES: Written or electronic comments and requests for a public hearing must be received by August 8, 2016.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–127199–15), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG–127199–15), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC., or sent electronically, via the Federal eRulemaking Portal at *http://www.regulations.gov* (IRS REG–127199–15).

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Ronald M. Gootzeit, (202) 317–6937; concerning submissions of comments and/or requests for a hearing, Regina Johnson, (202) 317–6901 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in this notice of proposed rulemaking has been previously reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) under control number 1545–1191. The estimated average annual recordkeeping burden per recordkeeper is 10 hours. The estimated reporting burden is being reported under Form 5472 (OMB # 1545–0123).

The collection of information in this proposed regulation is in sections 1.6038A–1 through 1.6038A–3 and 1.6038A–5. This information is required in order to provide the IRS with improved access to information that it needs to satisfy its obligations under U.S. tax treaties, tax information exchange agreements, and similar international agreements, as well as to strengthen the enforcement of U.S. tax laws. The likely respondents are foreign-owned domestic entities that are disregarded as separate from their owners.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by the Office of Management and Budget.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Background

Sections 301.7701–1 through 301.7701–3 ("the entity classification regulations") classify a business entity with two or more members as either a corporation or a partnership, and a business entity with a single owner as either a corporation or an entity disregarded as separate from its owner ("disregarded entity"). Certain domestic business entities, such as limited liability companies ("LLCs"), are classified by default as partnerships (if they have more than one member) or as disregarded entities (if they have only one owner) but are eligible to elect for federal tax purposes to be classified as corporations. Under special rules, an entity that is otherwise disregarded is not disregarded for certain excise and employment tax purposes. Section 301.7701–2(c)(2)(iv) and (v).

Some disregarded entities are not obligated to file a return or obtain an employer identification number ("EIN"). In the absence of a return filing obligation (and associated record maintenance requirements) or the identification of a responsible party as required in applying for an EIN, it is difficult for the United States to carry out the obligations it has undertaken in its tax treaties, tax information exchange agreements and similar international agreements to provide other jurisdictions with relevant information on U.S. entities with owners that are tax resident in the partner jurisdiction or otherwise have a tax nexus with respect to the partner jurisdiction.

Section 6001 of the Internal Revenue Code ("Code") provides that every person liable for any tax imposed by the Code, or for the collection thereof, shall keep such records, render such statements, make such returns and comply with such rules and regulations as the Secretary may from time to time prescribe, and that whenever in the judgment of the Secretary it is necessary, he may require any person, by notice served upon such person or by regulations, to make such returns, render such statements, or keep such records, as the Secretary deems sufficient to show whether or not such person is liable for tax. Thus, the Treasury Department and the IRS have broad authority under section 6001 of the Code to promulgate regulations to require the keeping of records and the reporting of information by persons who may be liable for any tax. The Code also requires many categories of persons to file returns, even if no tax is owed in a particular year. For example, all corporations organized in the United States must file annual income tax returns, which may include schedules requiring the identification of owners exceeding specified ownership thresholds. Moreover, foreign corporations engaged in a trade or business in the United States ("U.S. trade or business") must file annual income tax returns. Section 6012(a)(2); section 1.6012–2. Domestic partnerships must file information returns with schedules identifying each partner. Section 6031; section 1.6031(a)–1. In addition, domestic corporations that are at least 25% foreign-owned are subject to specific information reporting and record maintenance requirements. Section 6038A.

All entities, including disregarded entities, must have an EIN to file a required return. Section 6109(a)(1); *see* section 301.6109–1(a)(1)(ii)(C) and (b). An entity must also have an EIN in order to elect to change its classification. An entity that accepts its default classification and is not required to file a return need not obtain an EIN. Because a domestic single-member LLC is classified as a disregarded entity by default rather than by election and has no separate federal tax return filing requirements, there is typically no federal tax requirement for it to obtain an EIN. Other applicable federal or state laws may require an entity to obtain an EIN. For example, pursuant to federal law, financial institutions in the United States generally require an entity to have an EIN to open an account. *See* 31 CFR 1020.220(a)(1)(i)(A)(*4*).

An entity obtains an EIN by filing Form SS–4, Application for Employer Identification Number, in which the entity must identify a responsible party. The instructions to Form SS–4 define "responsible party" for an entity (including a disregarded entity) that is not traded on a public exchange or registered with the Securities and Exchange Commission as "the individual who has a level of control over, or entitlement to, the funds or assets in the entity that, as a practical matter, enables the individual, directly or indirectly, to control, manage, or direct the entity and the disposition of its funds and assets." The entity must also report any subsequent change in the responsible party. *See* section 301.6109–1(d)(2)(ii).

When an entity, such as an LLC, is classified as a corporation or a partnership for tax purposes, general ownership and accounting information is available to the IRS through the return filing and EIN application requirements. However, a disregarded entity is not subject to a separate income or information return filing requirement. Its owner is treated as owning directly the entity's assets and liabilities, and the information available with respect to the disregarded entity depends on the owner's own return filings, if any are required. For a disregarded entity that is formed in the United States and wholly owned by a foreign corporation, foreign partnership, or nonresident alien individual, generally no U.S. income or information return must be filed if neither the disregarded entity nor its owner received any U.S. source income or was engaged in a U.S. trade or business during the taxable year. Moreover, if a disregarded entity only receives certain types of U.S. source income, such as portfolio interest or U.S. source income that is fully withheld upon at source, its owner may not have a U.S. return filing requirement. Even in cases when the disregarded entity has an EIN, as well as in cases when income earned through a disregarded entity must be reported on its owner's return (for example, income from a U.S. trade or business), it may be difficult to associate the income with the disregarded entity based solely on the owner's return.

Although ownership and accounting information is generally available under the reporting requirements established by the U.S. federal tax system with respect to many types of domestic entities, the absence of specific return filing and associated recordkeeping requirements for foreign-owned, single-member domestic entities hinders law enforcement efforts and compliance with international standards of transparency and cooperation in the area of tax information exchange. These difficulties have been noted in reviews of the U.S. legal system by international organizations, including the Financial Action Task Force and the Global Forum on Transparency and Exchange of Information for Tax Purposes, which is affiliated with the Organisation for Economic Co-operation and Development. The lack of ready access to information on ownership of, and transactions involving, these entities also makes it difficult for the IRS to ascertain whether the entity or its owner is liable for any federal tax.

In general, section 6038A imposes reporting and recordkeeping requirements (together with certain procedural compliance requirements) on domestic corporations that are 25-percent foreign-owned. They are required to file an annual return on Form 5472, Information Return of a 25% Foreign-Owned U.S. Corporation or a Foreign Corporation Engaged in a U.S. Trade or Business (Under Sections 6038A and 6038C of the Internal Revenue Code), with respect to each related party with which the reporting corporation has had any "reportable transactions." *See* section 1.6038A–2. These corporations must keep the permanent books of account or records as required by section 6001 that are sufficient to establish the accuracy of the federal income tax return of the corporation, including information, documents, or records to the extent they may be relevant to determine the correct U.S. tax treatment of transactions with related parties. *See* section 1.6038A–3.

Explanation of Provisions

These proposed regulations would amend section 301.7701–2(c) to treat a domestic disregarded entity that is wholly owned by one foreign person as a domestic corporation separate from its owner for the limited purposes of the reporting and record maintenance requirements (including the associated procedural compliance requirements) under section 6038A. As with the existing special rules with respect to employment and excise taxes, these proposed regulations would not alter the framework of the existing entity classification regulations, including the treatment of certain entities as disregarded. These regulations are intended to provide the IRS with improved access to information that it needs to satisfy its obligations under U.S. tax treaties, tax information exchange agreements and similar international agreements, as well as to strengthen the enforcement of U.S. tax laws.

Because the proposed regulations would treat the affected domestic entities as foreign-owned domestic corporations for the specific purposes of section 6038A under the proposed regulations, and because such entities are foreign-owned, they would be reporting corporations within the meaning of section 6038A. Consequently, they would be required to file the Form 5472 information return with respect to reportable transactions between the entity and its foreign owner or other foreign related parties (transactions that would have been regarded under general U.S. tax principles if the entity had been, in fact, a corporation for U.S. tax purposes) and would also be required to maintain records sufficient to establish the accuracy of the information return and the correct U.S. tax treatment of such transactions. In addition, because these entities would have a filing obligation, they would be required to obtain an EIN by filing a Form SS–4 that includes responsible party information.

To ensure that such entities are required to report all transactions with foreign related parties, these regulations would specify as an additional reportable category of transaction for these purposes any transaction within the meaning of section 1.482–1(i)(7) (with such entities being treated as separate taxpayers for the purpose of identifying transactions and being subject to requirements under section 6038A) to the extent not already covered by another reportable category. The term "transaction" is defined in section 1.482–1(i)(7) to include any sale, assignment, lease, license, loan, advance, contribution, or other transfer of any interest in or a right to use any property or money, as well as the performance of any services for the benefit of, or on behalf of, another taxpayer. For example, under these proposed regulations, contributions and distributions would be considered reportable transactions with respect to such entities. Accordingly, a transaction between such an entity and its foreign owner (or another disregarded entity of the same owner) would be considered a reportable transaction for purposes of the section 6038A reporting and record maintenance requirements, even though, because it involves a disregarded entity, it generally would not be considered a transaction for other purposes, such as making an adjustment under section 482. The penalty provisions associated with failure to file the Form 5472 and failure to maintain records would apply to these entities as well.

The proposed regulations would also provide that the exceptions to the record maintenance requirements in section 1.6038A–1(h) and (i) for small corporations and *de minimis* transactions will not apply to these entities.

Consistent with the changes contemplated by these proposed regulations, the IRS is also considering modifications to corporate, partnership, and other tax or information returns (or their instructions) to require the filer of these returns to identify all the foreign and domestic disregarded entities it owns.

The proposed regulations would impose a filing obligation on a foreign-owned disregarded entity for reportable transactions it engages in even if its foreign owner already has an obligation to report the income resulting from those transactions—for example, transactions resulting in income effectively connected with the conduct of a U.S. trade or business. The Treasury Department and the IRS request comments on possible alternative methods for reporting the disregarded entity's transactions in such cases.

Proposed Effective/Applicability Date

The regulations are proposed to be applicable for taxable years ending on or after the date that is 12 months after the date these regulations are published as final regulations in the **Federal Register**.

Special Analyses

Certain IRS regulations, including this one, are exempt from the requirements of Executive Order 12866, as supplemented and reaffirmed by Executive Order 13563. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) and (d) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations. Pursuant to the Regulatory Flexibility Act (5 U.S.C. chapter 6), it is hereby certified that this regulation will not have a significant economic impact on a substantial number of small entities. Accordingly, a regulatory flexibility analysis is not required. This certification is based on the fact that these regulations will primarily affect a small number of foreign-owned domestic entities that do not themselves otherwise have a U.S. return filing requirement, and that the requirement to file a return for these entities will not impose a significant burden on them. Pursuant to section 7805(f), this notice of proposed rulemaking has been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small entities.

Comments and Requests for a Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any comments that are submitted timely to the IRS as prescribed in this preamble under the **ADDRESSES** heading. The Treasury Department and the IRS request comments on aspects of the proposed rules for which additional guidance is desired. All comments will be available at *www.regulations.gov* or upon request. A public hearing will be scheduled if requested in writing by any person that timely submits written comments. If a public hearing is scheduled, then notice of the date, time, and place for the public hearing will be published in the **Federal Register**.

Drafting Information

The principal author of these regulations is Ronald M. Gootzeit, Office of Associate Chief Counsel (International). However, other personnel from the Treasury Department and the IRS participated in their development.

List of Subjects

26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 301

Employment taxes, Estate taxes, Excise taxes, Gift taxes, Income taxes, Penalties, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR parts 1 and part 301 are proposed to be amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 is amended by revising the entries for §§ 1.6038A–1 and 1.6038A–2 to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

* * * * *

Section 1.6038A–1 also issued under 26 U.S.C. 6001.

Section 1.6038A–2 also issued under 26 U.S.C. 6001.

* * * * *

■ **Par. 2.** Section 1.6038A–1 is amended as follows:

■ 1. Paragraph (c)(1) is amended by adding a sentence at the end of the paragraph.

■ 2. The first sentence of paragraph (h) is revised.

■ 3. The first sentence of paragraph (i)(1) is revised.

■ 4. Paragraph (n)(1) is amended by adding a sentence at the end of the paragraph.

■ 5. Paragraph (n)(2) is amended by adding a sentence at the end of the paragraph.

The additions and revisions read as follows:

§ 1.6038A–1 General requirements and definitions.

* * * * *

(c) * * *

(1) * * * A domestic business entity that is wholly owned by one foreign person and that is otherwise classified under § 301.7701–3(b)(1)(ii) of this chapter as disregarded as an entity separate from its owner is treated as an entity separate from its owner and classified as a domestic corporation for purposes of section 6038A. *See* § 301.7701–2(c)(2)(vi) of this chapter.

* * * * *

(h) *Small corporation exception.* A reporting corporation (other than an entity that is treated as a reporting corporation by reason of § 301.7701–2(c)(2)(vi) of this chapter) that has less than $10,000,000 in U.S. gross receipts for a taxable year is not subject to §§ 1.6038A–3 and 1.6038A–5 for that taxable year.* * *

(i) *Safe harbor for reporting corporations with related party transactions of de minimis value*—(1) *In general.* A reporting corporation (other than an entity that is treated as a reporting corporation by reason of § 301.7701–2(c)(2)(vi) of this chapter) is not subject to §§ 1.6038A–3 and 1.6038A–5 for any taxable year in which the aggregate value of all gross payments it makes to and receives from foreign related parties with respect to related party transactions (including monetary, nonmonetary consideration, and the value of transactions involving less than full consideration) is not more than $5,000,000 and is less than 10 percent of its U.S. gross income.* * *

* * * * *

(n) * * *

(1) * * * The last sentence of paragraph (c)(1) of this section (relating to certain domestic business entities), the parenthetical language in paragraph (h) of this section (relating to entities that are treated as reporting corporations by reason of § 301.7701–2(c)(2)(vi) of this chapter), and the parenthetical language in paragraph (i)(1) of this section (relating to entities that are treated as reporting corporations by reason § 301.7701–2(c)(2)(vi) of this chapter) apply to taxable years of such entities ending on or after the date that is 12 months after the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**.

(2) * * * Paragraphs (b)(3)(xi) and (b)(9) of this section and the last sentence of paragraph (d) of § 1.6038A–2 apply to taxable years of the entities described in § 301.7701–2(c)(2)(vi) of this chapter ending on or after the date that is 12 months after the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**.

* * * * *

■ **Par. 3.** Section 1.6038A–2 is amended as follows:

■ 1. In paragraph (b)(3)(ix), remove the word "and".

■ 2. In paragraph (b)(3)(x), remove the period at the end of the paragraph and add "; and" in its place.

■ 3. Add paragraph (b)(3)(xi).

■ 4. Add paragraph (b)(9).

■ 5. Add a sentence at the end of paragraph (d).

The additions and revisions read as follows:

§ 1.6038A–2 Requirements of return.

* * * * *

(b) * * *

(3) * * *

(xi) With respect to an entity that is treated as a reporting corporation by reason of § 301.7701–2(c)(2)(vi) of this chapter, any other transaction as defined by § 1.482–1(i)(7), such as amounts paid or received in connection with the formation, dissolution, acquisition and disposition of the entity, including contributions to and distributions from the entity.

* * * * *

(9) *Examples.* The application of paragraph (b)(3) of this section may be illustrated by the following examples:

Example 1. (i) In year 1, W, a foreign corporation, forms and contributes assets to X, a domestic limited liability company that does not elect to be treated as a corporation under § 301.7701–3(c) of this chapter. In year 2, W contributes funds to X. In year 3, X makes a payment to W. In year 4, X, in liquidation, distributes its assets to W.

(ii) In accordance with § 301.7701–3(b)(1)(ii) of this chapter, X is disregarded as an entity separate from W. In accordance with § 301.7701–2(c)(2)(vi) of this chapter, X is treated as an entity separate from W and classified as a domestic corporation for purposes of section 6038A. In accordance with paragraphs (a)(2) and (b)(3) of this section, each of the transactions in years 1 through 4 is a reportable transaction with respect to X. Therefore, X has a section 6038A reporting and record maintenance requirement for each of those years.

Example 2. (i) The facts are the same as in *Example 1* of this paragraph (b)(9) except that in year 1 W also forms and contributes assets to Y, another domestic limited liability company that does not elect to be treated as a corporation under § 301.7701–3(c) of this chapter. In year 1, X and Y form and contribute assets to Z, another domestic limited liability company that does not elect to be treated as a corporation under § 301.7701–3(c) of this chapter. In year 2, X transfers funds to Z. In year 3, Z makes a payment to Y. In year 4, Z distributes its assets to X and Y in liquidation.

(ii) In accordance with § 301.7701–3(b)(1)(ii) of this chapter, Y and Z are disregarded as entities separate from each other, W, and X. In accordance with § 301.7701–2(c)(2)(vi) of this chapter, Y, Z and X are treated as entities separate from each other and W, and are classified as domestic corporations for purposes of section 6038A. In accordance with paragraph (b)(3) of this section, each of the transactions in years 1 through 4 involving Z is a reportable transaction with respect to Z. Similarly, the contribution to Y in year 1, the payment to Y in year 3, and the distribution to Y in year 4 are reportable transactions with respect to Y. Moreover, X's funds transfer to Z in year 2 is a reportable transaction. Therefore, Z has a section 6038A reporting and record maintenance requirement for years 1 through 4, Y has a section 6038A reporting and record maintenance requirement for years 1, 3 and 4, and X has a section 6038A reporting and record maintenance requirement in year 2 in addition to its section 6038A reporting and record maintenance described in *Example 1 of this paragraph (b)(9).*

(d) * * * In the case of an entity that is treated as a reporting corporation by reason of § 301.7701–2(c)(2)(vi) of this chapter, Form 5472 must be filed at such time and in such manner as the Commissioner may prescribe in forms or instructions.

* * * * *

PART 301—PROCEDURE AND ADMINISTRATION

■ **Par. 4.** The authority citation for part 301 continues in part to read as follows:

Authority: 26 U.S.C. 7805 * * *

■ **Par. 5.** Section 301.7701–2 is amended by revising the last sentence of paragraph (a) and adding paragraphs (c)(2)(vi) and (e)(9) to read as follows:

§ 301.7701–2 Business entities; definitions.

(a) * * * But see paragraphs (c)(2)(iii) through (vi) of this section for special rules that apply to an eligible entity that is otherwise disregarded as an entity separate from its owner.

* * * * *

(c) * * *

(2) * * *

(vi) *Special rule for reporting under section 6038A*—(A) *In general.* An entity that is disregarded as separate from its owner for any purpose under this section is treated as an entity separate from its owner and classified as a corporation for purposes of section 6038A if—

(*1*) The entity is a domestic entity; and

(*2*) One foreign person has direct or indirect sole ownership of the entity.

(B) *Definitions*—(*1*) *Indirect sole ownership.* For purposes of paragraph (c)(2)(vi)(A)(*2*) of this section, indirect sole ownership means ownership by one person entirely through one or more entities disregarded as separate from their owners or through grantor trusts, regardless of whether any such disregarded entity or grantor trust is domestic or foreign.

(*2*) *Entity disregarded as separate from its owner.* For purposes of this paragraph (c)(2)(vi)(B), an entity disregarded as separate from its owner is an entity described in paragraph (c)(2)(i) of this section, without regard to the exceptions provided in paragraphs (c)(2)(ii) though (vi) of this section.

(*3*) *Grantor trust.* For purposes of this paragraph (c)(2)(vi)(B), a grantor trust is any portion of a trust that is treated as owned by the grantor or another person under subpart E of subchapter J of chapter 1 of the Code.

* * * * *

(e) * * *

(9) *Reporting required under section 6038A.* Paragraph (c)(2)(vi) of this section applies to taxable years ending on or after the date that is 12 months after the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register.**

John Dalrymple,

Deputy Commissioner for Services and Enforcement.

[FR Doc. 2016–10852 Filed 5–6–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 110

[Docket Number USCG–2015–0729]

RIN 1625–AA01

Port of Miami Anchorage Area; Atlantic Ocean, Miami Beach, FL

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to revise the Miami Anchorage. Under the proposal, the Miami Anchorage would be divided into two separate anchorage areas. This action is necessary to reduce potential damage to threatened coral posed by anchoring vessels. This proposed revision would update the regulation to clarify the regulatory text and to reflect the establishment of two anchorage areas instead of one area currently in place. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before July 11, 2016.

ADDRESSES: You may submit comments identified by docket number USCG–2015–0729 using the Federal eRulemaking Portal at *http://www.regulations.gov.* See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email LT Ruth Sadowitz, Sector Miami Waterways Management Division, U.S. Coast Guard; telephone 305–535–4307, email *Ruth.A.Sadowitz@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR	Code of Federal Regulations
DHS	Department of Homeland Security
FDEP	Florida Department of Environmental Protection
FR	Federal Register
NMFS	National Marine Fisheries Service
NPRM	Notice of proposed rulemaking
§	Section
SEFCRI	South East Florida Coral Reef Initiative
U.S.C.	United States Code

II. Background, Purpose, and Legal Basis

On December 1, 2015, the Coast Guard published a Notice of Study and request for comments (80 FR 75020) advising that we were evaluating an amendment to the Miami Anchorage (33 CFR 110.188) that would divide the anchorage into two separate anchorage areas. The possible modification of the anchorage area was designed in coordination with local stakeholders in an effort to mitigate damage to coral that may be caused by vessels anchoring. Comments provided by these stakeholders, academic research, and environmental reports addressed a number of options to potentially reduce the likelihood of damage to the Florida Reef in the Miami Anchorage. Those documents, which may be found in the docket, influenced this Coast Guard's selection of the anchorage modification proposed in this notice.

In response to the Notice of Study, the Coast Guard received four comments. The first comment was from the non-profit organization, Miami Waterkeeper. Miami Waterkeeper supports the modifications to the anchorage area as those modifications would both better protect threatened species and critical coral habitat and still allow for safe navigation.

The second comment came from the National Marine Fisheries Service—Habitat Conservation Division (NFMS). NMFS stated that they support relocating the anchorage area in order to reduce continued degradation of the coral reef and, ultimately, allow for restoration of the reef.

The third comment was from NOAA. On December 1, 2015, NOAA submitted a comment to verify the coordinates of the possible amended anchorage area listed in the notice. The coordinates for the location of the amended anchorage areas were published incorrectly. The latitudinal coordinates were inadvertently published in the longitude column and vice versa. However, the numerical coordinates published in the chart was correct. The error has been corrected in this notice of proposed rulemaking (NPRM).

The final comment came from Florida Department of Environmental Protection (FDEP). FDEP commented that the Coast Guard erred when it stated the genesis for the division of the anchorages was a SEFCRI report. While the SEFCRI report was instrumental to the evaluation of the current Miami Anchorage, the two anchorage solution was originally discussed in an academic paper authored by Lauren Waters, a FDEP employee. This paper can be found in the docket.

The comments received in response to the notice were positive or addressed non-substantive errors in the notice. The Coast Guard is therefore proceeding with a proposal to revise the Miami Anchorage under the authority of 33 U.S.C. 471, 1221 through 1236, 2071, 33 CFR 1.05–1 and Department of Homeland Security Delegation No. 0170.1.

III. Discussion of Proposed Rule

The Coast Guard proposes to revise the Miami Anchorage by dividing the anchorage into two separate anchorage areas and clarifying text throughout the regulation. This revision is intended to reduce threats to protected coral without compromising the ability of vessels to anchor safely. Although the two separate anchorages encompass a smaller area, they allow for the facilitation of safe anchorage of both shallow and deep draft vessels. The amended coordinates would establish two anchorages with a combined area of approximately 1.5 square miles thereby reducing the total anchorage area by approximately 3 square nautical miles. The amended anchorage areas would be established with the following coordinates:

SMALL WESTERN ANCHORAGE

[Approximate water depths: 45 ft]

	Latitude	Longitude
NW Corner	25°47′57.687″ N	080°05′37.225″ W.
NE Corner	25°47′57.341″ N	080°05′26.466″ W.
SE Corner	25°46′31.443″ N	080°05′27.069″ W.
SW Corner	25°46′31.557″ N	080°05′37.868″ W.

LARGE EASTERN ANCHORAGE

[Approximate water depths: 120 ft]

	Latitude	Longitude
NW Corner	25°48′13.841″ N	080°04′59.155″ W.
NE Corner	25°48′04.617″ N	080°04′04.582″ W.
SE Corner	25°46′32.712″ N	080°04′28.387″ W.
SW Corner	25°46′32.767″ N	080°04′59.775″ W.

Additional minor revisions to the Miami Anchorage regulation are also proposed to pluralize the anchorage grounds that would be established and to clarify existing regulation text.

IV. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and Executive Orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This NPRM has not been designated a "significant regulatory action," under Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget.

This regulatory action determination is based on relatively minor changes to the existing Miami Anchorage regulation. This proposed regulation would create two separate anchorage areas with a combined total of 1.5 square miles of anchorage; while this does reduce the total anchorage area, the ability of shallow and deep draft vessels to safely anchor should not be impacted. This proposed regulation would clarify other regulatory text, but no other substantive changes are proposed.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to use the anchorage may be small entities, for the reasons stated in section IV.A above, this proposed rule would not have a significant economic impact on any vessel owner or operator.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), we want to assist small entities in understanding this proposed rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

This proposed rule would not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this proposed rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this proposed rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves reducing an anchorage. Normally such actions are categorically excluded from further review under paragraph 34(f) of Figure 2–1 of Commandant Instruction M16475.lD. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov.* If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

Documents mentioned in this NPRM as being available in the docket, and all public comments, will be in our online docket at *http://www.regulations.gov* and can be viewed by following that Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

List of Subjects in 33 CFR Part 110

Anchorage grounds.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 110 as follows:

PART 110—ANCHORAGES

■ 1. The authority citation for part 110 continues to read as follows:

Authority: 33 U.S.C. 471, 1221 through 1236, 2071; 33 CFR 1.05–1; Department of Homeland Security Delegation No. 0170.1.

■ 2. Revise § 110.188 to read as follows:

§ 110.188 Atlantic Ocean off Miami and Miami Beach, FL.

(a) *The anchorage grounds.* (1) *Anchorage A.* All area of the Atlantic Ocean, encompassed by a line beginning at 25°47′57.687″ N., 080°05′37.225″ W., thence east to 25°47′57.341″ N., 080°05′26.466″ W., thence south to 25°46′31.443″ N., 080°05′27.069″ W., thence west to 25°46′31.557″ N., 080°05′37.868″ W., thence back to origin.

(2) *Anchorage B.* All area of the Atlantic Ocean, encompassed by a line beginning at 25°48′13.841″ N., 080°04′59.155″ W., thence east to 25°48′04.617″ N., 080°04′04.582″ W., thence south to 25°46′32.712″ N., 080°04′28.387″ W., thence west to 25°46′32.767″ N., 080°04′59.775″ W., thence back to origin.

(b) *The rules and regulations.* (1) Except in cases of emergency, no vessel shall be anchored in the Atlantic Ocean in the vicinity of the entrances to the approach channels leading to the cities of Miami Beach and Miami, Fl., outside of the anchorage grounds defined and established.

(2) Any vessel anchoring under circumstances of emergency outside of either anchorage ground shall be shifted to a new berth within the grounds immediately after the emergency ceases.

(3) All vessels seeking to anchor shall lie at anchor with as short a cable as conditions will permit.

(4) A vessel, upon being notified to move into the anchorage limits or to shift its position on an anchorage ground, must get underway at once or signal for a tug and must change position as directed with reasonable promptness.

(5) Whenever the maritime or commercial interests of the United States so require, the Captain of the Port, U.S. Coast Guard, Miami, Florida, is hereby empowered to shift the position of any vessel anchored on an anchorage ground or outside thereof, or any vessel moored or anchored so as to impede or obstruct vessel movements or obstruct or interfere with range lights.

(6) Vessels carrying explosives shall be anchored only under a written permit issued by the Captain of the Port and at such point as she or he may direct.

(7) Vessels carrying explosives shall be at all times under the charge or command of a competent person and must display by day a red flag, of not less than 16 square feet, at the masthead or not less than 10 feet above the upper

deck if the vessel has no mast; at night a red light shall be displayed in the positions specified for the red flag.

(8) Nothing in this paragraph shall be construed as relieving the owner or person in charge of any vessel from penalties for obstructing navigation, or for obstructing or interfering with range lights, or for not complying with navigation laws in regard to lights, fog signals, or other aids to navigation, or for otherwise violating the law.

(9) All vessels desiring to use an Anchorage must notify the Coast Guard Captain of the Port, via the Biscayne Bay Pilots on VHF–FM Channel 12 or 16.

(10) All vessels anchored within the anchorage grounds shall maintain a 24–hour bridge watch by an English speaking licensed or credentialed deck officer monitoring VHF–FM Channel 16. This individual shall perform frequent checks of the vessel's position to ensure the vessel is not dragging anchor.

(11) Vessels experiencing casualties such as a main propulsion, main steering, or anchoring equipment malfunction or which are planning to perform main propulsion engine repairs or maintenance, shall immediately notify the Coast Guard Captain of the Port via the Coast Guard Sector Miami on VHF–FM Channel 16.

(12) The Coast Guard Captain of the Port may close the anchorage grounds and direct vessels to depart an anchorage during periods of adverse weather or at other times as deemed necessary in the interest of port safety.

Dated: May 4, 2016.

S.A. Buschman,

Rear Admiral, U.S. Coast Guard, Commander, Seventh Coast Guard District.

[FR Doc. 2016–10850 Filed 5–9–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2016–0205]

RIN 1625–AA09

Drawbridge Operation Regulation; Atlantic Intracoastal Waterway, New Smyrna Beach, FL

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to modify the operating schedule that governs the Coronado Beach (George Musson) Bridge across the Atlantic Intracoastal Waterway, mile 845, at New Smyrna Beach, FL. This proposed rule would change the existing 20 minute opening schedule to a 30 minute opening schedule between 7 a.m. and 7 p.m. This modification would provide some relief to vehicle traffic congestion and would have little to no effect on navigation. The proposed rule will also add the local bridge name to the regulation published in the Code of Federal Regulations, George Musson/ Coronado Beach (SR44). We invite your comments on this proposed rulemaking.

DATES: Comments and related material must reach the Coast Guard on or before July 11, 2016.

ADDRESSES: You may submit comments identified by docket number USCG–2016–0205 using Federal eRulemaking Portal at *http://www.regulations.gov.* See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or email LT Allan Storm with the Coast Guard; telephone 904–714–7616, email *allan.h.storm@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR	Code of Federal Regulations
DHS	Department of Homeland Security
FR	Federal Register
NPRM	Notice of proposed rulemaking
§	Section
U.S.C.	United States Code

II. Background, Purpose and Legal Basis

On April 25, 2015, the City of New Smyrna Beach requested that the Coast Guard review the current operating schedule for the Coronado Beach (George Musson) Bridge (SR 44) to determine whether a change could be made to improve vehicle traffic flow in the area. The bridge owner, Florida Department of Transportation, was also consulted on this issue and it concurred with the recommendation to change the current schedule requiring an opening every 20 minutes to a schedule requiring an opening every 30 minutes all days of the week.

The George Musson Bridge across the Atlantic Intracoastal Waterway, mile 845, at New Smyrna Beach, FL is a double leaf bascule bridge. It has a vertical clearance of 24 feet in the closed position at mean high water and a horizontal clearance of 90 feet.

Presently, in accordance with 33 CFR 117.261(h), the Coronado Beach bridge (SR 44), also known as the George Musson Bridge, at mile 845 at New Smyrna Beach, FL shall open on signal, except that from 7 a.m. until 7 p.m., each day of the week, the draw need only open on the hour, twenty minutes past the hour and forty minutes past the hour. The Coast Guard proposes this rulemaking under authority in 33 U.S.C. 499.

III. Discussion of Proposed Rule

The Coast Guard proposes to amend 33 CFR 117.261, paragraph h, regarding the operation of the George Musson/ Coronado Beach (SR 44) Bridge, Atlantic Intracoastal Waterway, mile 845, at New Smyrna Beach, FL. The proposed regulation would allow the bridge to open twice an hour rather than three times an hour to reduce vehicle traffic backups. In addition to changing the operating schedule, this regulation would add the local name of this bridge, George Musson, to the CFR. This regulation change will not have a significant impact on navigation in this area.

As per, 33 CFR 117.261(a) *General:* Public vessels of the United States and tugs with tows must be passed through the drawspan of each drawbridge listed in this section at anytime. These proposed changes will meet the reasonable needs of vessel traffic passing through the Bridge while taking into account the reasonable needs of other modes of transportation. Vessels not requiring an opening may pass at any time.

IV. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and Executive Orders related to rulemaking. Below we summarize our analyses based on these statutes and Executive Orders and we also discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This NPRM has not been designated a "significant regulatory action," under Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget.

This regulatory action determination is based on the limited impact that it is anticipated to have on vessel traffic on the Atlantic Intracoastal Waterway. This proposed rule will change the opening schedule from three times an hour to two times an hour. Currently, bridge logs show that the Bridge generally opens twice an hour because vessel traffic volumes do not require three openings per hour. Therefore, there should be no actual change to the number of bridge openings per hour. Also, vessels that can transit under the bridge without an opening may do so. Emergency vessels and tugs with tows can still request openings at any time.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended, requires federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the bridge may be small entities, for the reasons stated in section IV.A above this proposed rule would not have a significant economic impact on any vessel owner or operator.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), we want to assist small entities in understanding this proposed rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

This proposed rule would call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520.).

D. Federalism and Indian Tribal Government

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this proposed rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in E.O. 13132.

Also, this proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this proposed rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this proposed rule will not result in such an expenditure, we do discuss the effects of this proposed rule elsewhere in this preamble.

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves the operating regulations or procedures for drawbridges. Normally such actions are categorically excluded from further review, under figure 2–1, paragraph (32)(e), of the Instruction.

Under figure 2–1, paragraph (32)(e), of the Instruction, an environmental analysis checklist and a categorical exclusion determination are not required for this rule. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov*. If your material cannot be submitted using *http://www.regulations.gov*, contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

Documents mentioned in this NPRM as being available in the docket, and all public comments, will be in our online docket at *http://www.regulations.gov* and can be viewed by following that Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

List of Subjects in 33 CFR Part 117

Bridges.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

■ 1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 33 CFR 1.05–1; and Department of Homeland Security Delegation No. 0170.1.

■ 2. Revise § 117.261(h) to read as follows:

§ 117.261 Atlantic Intracoastal Waterway from St. Marys River to Key Largo.

* * * * *

(h) *George Musson/Coronado Beach (SR 44) bridge, mile 845 at New Smyrna Beach.* The George Musson/Coronado Beach (SR 44) bridge, mile 845, shall open on signal, except that from 7 a.m. to 7 p.m., the draw shall open on the hour and half-hour, seven days a week.

* * * * *

Dated: May 4, 2016.

S.A. Buschman,

Rear Admiral, U.S. Coast Guard, Commander, Seventh Coast Guard District.

[FR Doc. 2016–10919 Filed 5–9–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2015–0343]

RIN 1625–AA09

Drawbridge Operation Regulation; Atlantic Intracoastal Waterway, Little River to Savannah River

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to modify the operating schedule that governs the Lady's Island Bridge, across the Beaufort River, Mile 536.0 at Beaufort, SC. This modification would allow Lady's Island Bridge to remain closed during peak vehicular traffic times. The bridge owner, South Carolina Department of Transportation, requested this action to assist in reducing traffic caused by bridge openings.

DATES: Comments and related material must reach the Coast Guard on or before July 11, 2016.

ADDRESSES: You may submit comments identified by docket number USCG–2015–0343 using Federal eRulemaking Portal at *http://www.regulations.gov.*

See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or email Lieutenant John Z. Downing at telephone 843–740–3184, email *John.Z.Downing@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR	Code of Federal Regulations
DHS	Department of Homeland Security
E.O.	Executive order
FR	Federal Register
NPRM	Notice of proposed rulemaking
SNPRM	Supplemental notice of proposed rulemaking
Pub. L.	Public Law
§	Section
U.S.C.	United States Code

II. Background, Purpose and Legal Basis

The City of Beaufort, South Carolina requested that the bridge owner and the U.S. Coast Guard modify the operating schedule for Lady's Island Bridge to reduce vehicular traffic in the City of Beaufort and surrounding communities. On February 17th, 2015, Coast Guard Sector Charleston Waterways Management (WWM) staff observed the Lady's Island Bridge operations between the hours of 6 a.m. and 10 a.m. During the observation period, the staff discussed potential changes with the Bridge owner, South Carolina Department of Transportation. Additionally, WWM met with the Beaufort County South Carolina traffic manager to discuss bridge opening impacts.

On August 5th, 2015, a Temporary Deviation, entitled, "Drawbridge Operation Regulations: Atlantic Intracoastal Waterway, Little River to Savannah River," was published in the **Federal Register** [USCG–2015–0343] [80 FR 46492] to evaluate whether changing the bridge opening schedule would assist in reducing traffic congestion. This deviation was in effect through November 3rd, 2015.

During the deviation period the Coast Guard received six comments, five of which recommended retaining the operating schedule currently found at 33 CFR 117.911(f). One comment proposed a bridge opening during the morning and afternoon vehicular traffic rush hours. Based on the Coast Guard's observation of bridge use during peak traffic hours, the existing schedule would continue to create an unreasonable amount of vehicle traffic during morning and afternoon commutes and generally during daylight hours. One comment further suggested not changing the existing schedule during certain times of the year when increased vessel traffic is expected. The Coast Guard adopted this proposal because would meet the reasonable needs of navigation.

The Lady's Island Bridge in Beaufort, South Carolina has a vertical clearance of 30 feet at Mean High Water in the closed position. The existing drawbridge schedule can be found in 33 CFR 117.911(f).

III. Discussion of Proposed Rule

The Coast Guard proposes to amend 33 CFR 117.911(f). This proposed regulation would modify timeframes the bridge may remain closed. It would extend the morning closure period, when the bridge is authorized to remain closed, by an additional half hour and the afternoon closure period by an additional hour. It would also set an hourly opening schedule between 9 a.m. and 3 p.m. when the Bridge will open on the hour, thereby reducing hourly openings from twice an hour to once an hour during daytime hours, Monday through Friday, except Federal holidays. This proposed regulation would reduce vehicle backups without unreasonably restricting vessel traffic, thereby balancing the needs of both modes of transportation. No changes to the existing regulation will be implemented during the months of April, May, October and November because higher vessel traffic volumes exist during these time periods. At all other times, this bridge will open on signal.

The South Carolina Department of Transportation, the bridge owner, has no objections to this proposed schedule.

IV. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and executive orders (E.O.s) related to rulemaking. Below we summarize our analyses based on these statutes and E.O.s and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

E.O.s 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This NPRM has not been designated a "significant regulatory action," under E.O. 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget.

This regulatory action determination is based on vessels being able to plan voyages that require transiting the bridge during the scheduled opening periods or, when capable of doing so, vessels may transit under the bridge at any time.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended, requires federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the bridge may be small entities, for the reasons stated in section IV.A above this proposed rule would not have a significant economic impact on any vessel owner or operator.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

This proposed rule would call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520.).

D. Federalism and Indian Tribal Government

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this proposed rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in E.O. 13132.

Also, this proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this proposed rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this proposed rule will not result in such an expenditure, we do discuss the effects of this proposed rule elsewhere in this preamble.

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA)(42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This proposed rule simply promulgates the operating regulations or procedures for drawbridges. Normally such actions are categorically excluded from further review, under figure 2–1, paragraph (32)(e), of the Instruction.

Under figure 2–1, paragraph (32)(e), of the Instruction, an environmental analysis checklist and a categorical exclusion determination are not required for this rule. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov*. If your material cannot be submitted using *http://www.regulations.gov*, contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

Documents mentioned in this notice, and all public comments, are in our online docket at *http://www.regulations.gov* and can be viewed by following that Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

List of Subjects in 33 CFR Part 117

Bridges.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

■ 1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 33 CFR 1.05–1; Department of Homeland Security Delegation No. 0170.1.

■ 2. In § 117.911, revise paragraph (f) to read as follows:

* * * * *

(f) The Lady's Island Bridge (Woods Memorial), across the Beaufort River, Mile 536.0 at Beaufort. The draw shall operate as follows:

(1) On Monday through Friday, except Federal holidays:

(i) From 6:30 a.m. to 9 a.m. and 3 p.m. to 6 p.m., the draw need not open to navigation; and,

(ii) Between 9 a.m. to 3 p.m., the draw need open only on the hour.

(2) During the months of April, May, October, and November from Monday through Friday, except Federal holidays, the Lady's Island Bridge (Woods Memorial) shall operate as follows:

(i) From 7 a.m. to 9 a.m. and 4 p.m. to 6 p.m., the draw need not open to navigation; and,

(ii) Between 9 a.m. to 4 p.m., the draw need open only on the hour and half-hour.

(3) At all other times the draw shall open on signal.

Dated: May 4, 2016.

S.A. Buschman,

Rear Admiral, U.S. Coast Guard, Commander, Seventh Coast Guard District.

[FR Doc. 2016–10920 Filed 5–9–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2015–0768]

RIN 1625–AA09

Drawbridge Operation Regulation; Atlantic Intracoastal Waterway and Indian Creek, Miami, FL.

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes modifying the operating schedule that governs the West 79th Street Bridge across the Atlantic Intracoastal Waterway mile 1084.6, Miami, FL and the operating schedule that governs the East 79th Street Bridge across Miami Beach Channel, Miami, FL. This action will place the East and West 79th Street Bridges across Miami Beach Channel and Atlantic Intracoastal Waterway, Miami, FL on a twice an hour opening schedule between 7 a.m. and 7 p.m., Monday through Friday, except Federal holidays. This action is intended to reduce vehicular traffic caused by these bridges opening on demand.

DATES: Comments and related material must reach the Coast Guard on or before July 11, 2016.

ADDRESSES: You may submit comments identified by docket number USCG–2015–0768 using the Federal eRulemaking Portal at *http://www.regulations.gov.* See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or email Mr. Michael Lieberum of the Coast Guard; telephone 305–415–6744, email *Michael.b.lieberum@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR	Code of Federal Regulations
DHS	Department of Homeland Security
FR	Federal Register
NPRM	Notice of Proposed Rulemaking
§	Section Symbol
U.S.C.	United States Code
FDOT	Florida Department of Transportation
AICW	Atlantic Intracoastal Waterway

II. Background, Purpose and Legal Basis

The East and West 79th Street Bridges currently open on signal, pursuant to 33 CFR 117.5, which results in frequent openings that restrict vehicle traffic during the day, especially during morning and afternoon rush hour traffic. The Florida Department of Transportation (FDOT), the bridge owner, and the City of North Bay Village requested a change to the current operating schedule for both bridges to allow for scheduled openings twice an hour during peak traffic times. Bridge logs indicate these bridges open up to four times an hour or more during peak travel times, which results in frequent vehicular traffic disruptions.

This proposed regulation would reduce vehicle traffic backups without unreasonably restricting vessel traffic by scheduling two openings per hour during peak traffic times, thereby balancing the needs of both modes of transportation.

Additionally, other bridges on this section of the Intracoastal Waterway and Miami Channel open two times per hour. The proposed scheduled openings will align the 79th Street bridge openings with other bridges on the Intracoastal, namely, the Broad Causeway Bridge to the North (33 CFR 117.261(mm)) and The Venetian Causeway Bridge to the South (33 CFR 117.261(nn)), thereby allowing vessels to plan voyages during opening times and vehicles to schedule commutes around these openings.

The East 79th Street Bridge across Miami Beach Channel, Miami, FL has a vertical clearance of 25 feet at MHW in the closed to navigation position and a horizontal clearance of 60 feet between fenders.

The West 79th Street Bridge across the Atlantic Intracoastal Waterway mile 1084.6, Miami, FL has a vertical clearance of 25 feet at MHW in the closed to navigation position and a horizontal clearance of 90 feet between fenders.

III. Discussion of Proposed Rule

The Coast Guard proposes to amend 33 CFR 117.261. The Coast Guard will add paragraph (mm1) to this section. Under this proposed regulation, the draw of the West 79th Street Bridges, at Miami, Florida would open twice an hour, once on the hour and once on the half-hour, Monday through Friday between the hours of 7 a.m. and 7 p.m. During nights and weekends and on Federal holidays, the Bridge would open on signal.

The Coast Guard further proposes to add section 117.304 to title 33 of the CFR. This section will be entitled "Miami Beach Channel" and would add the schedule for the East 79th Street Bridge that will be identical to the proposed schedule for the West 79th Street Bridge stated above.

IV. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and executive orders (E.O.s) related to rulemaking. Below we summarize our analyses based on these statutes and E.O.s and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

E.O.s 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This NPRM has not been designated a "significant regulatory action," under E.O. 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget.

This regulatory action determination is based on vessels being able to plan voyages that require transiting the bridge during the scheduled opening periods or, when capable of doing so, vessels may transit under the bridge at any time. This rule will further meet the reasonable needs of navigation while taking into consideration the reasonable needs of vehicular traffic.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended, requires federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the bridge may be small entities, for the reasons stated in section IV.A above this proposed rule would not have a significant economic impact on any vessel owner or operator.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), we want to assist small entities in understanding this proposed rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

This proposed rule would call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520.).

D. Federalism and Indian Tribal Government

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this proposed rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in E.O. 13132.

Also, this proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this proposed rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this proposed rule will not result in such an expenditure, we do discuss the effects of this proposed rule elsewhere in this preamble.

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This proposed rule simply promulgates the operating regulations or procedures for drawbridges. Normally such actions are categorically excluded from further review, under figure 2–1, paragraph (32)(e), of the Instruction.

Under figure 2–1, paragraph (32)(e), of the Instruction, an environmental analysis checklist and a categorical exclusion determination are not required for this rule. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov*. If your material cannot be submitted using *http://www.regulations.gov*, contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

Documents mentioned in this notice, and all public comments, are in our online docket at *http://www.regulations.gov* and can be viewed by following that Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

List of Subjects in 33 CFR Part 117

Bridges.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

■ 1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 33 CFR 1.05–1; Department of Homeland Security Delegation No. 0170.1.

■ 2. In § 117.261, add paragraph (mm1) to read as follows:

§ 117.261 Atlantic Intracoastal Waterway from St. Marys River to Key Largo.

* * * * *

(mm1) West 79th Street Bridge. The draw of the West 79th Street Bridge, at Miami, Florida will open on signal, except that from 7 a.m. to 7 p.m. Monday through Friday, except Federal holidays, the draw need only open on the hour and half hour.

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■ 3. Add § 117.304 to read as follows:

§ 117.304 Miami Beach Channel.

The draw of the East 79th Street bridge, at Miami, Florida will open on signal, except that from 7 a.m. to 7 p.m. Monday through Friday, except Federal holidays, the draw need only open on the hour and half hour.

Dated: May 4, 2016.

S.A. Buschman,

Rear Admiral, U.S. Coast Guard, Commander, Seventh Coast Guard District.

[FR Doc. 2016–10921 Filed 5–9–16; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2015–0501; FRL–9946–14–Region 4]

Air Plan Approval and Disapproval; North Carolina: New Source Review for Fine Particulate Matter ($PM_{2.5}$)

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve, in part, and disapprove, in part, changes to the North Carolina State Implementation Plan (SIP), provided by the North Carolina Department of Environmental Quality (NC DEQ) through the Division of Air Quality, to EPA in submittals dated May 16, 2011 (two separate submittals), and September 5, 2013. These SIP submittals modify North Carolina's New Source Review (NSR)—Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NNSR)—permitting regulations and include the adoption of some federal requirements regarding implementation of the fine particulate matter ($PM_{2.5}$) national ambient air quality standards (NAAQS) through the NSR permitting program. As a result of the proposed disapproval of a portion of the State's NSR requirements, EPA is also proposing to approve, in part, and disapprove, in part, the PSD elements of North Carolina's infrastructure SIP submittals for the 2008 lead, 2008 8-hour ozone, 2010 sulfur dioxide (SO_2), 2010 nitrogen dioxide (NO_2) and the 2012 $PM_{2.5}$ NAAQS, and to convert the Agency's previous conditional approvals of the PSD elements of North Carolina's infrastructure SIP submittals for the 1997 Annual $PM_{2.5}$ and 2006 24-hour $PM_{2.5}$ NAAQS to partial approvals and partial disapprovals. This proposed partial disapproval, if finalized, will trigger the requirements for EPA to promulgate a Federal Implementation Plan (FIP) no later than two years from the date of the disapproval unless the State corrects the deficiencies through a SIP revision and EPA approves the SIP revision before EPA promulgates such a FIP.

DATES: Comments must be received on or before June 9, 2016.

ADDRESSES: Submit your comments, identified by Docket ID No EPA–R04–OAR–2015–0501 at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from Regulations.gov. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the Web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Joel Huey of the Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. Mr. Huey can be reached by telephone at (404) 562–9104 or via electronic mail at *huey.joel@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. What are the actions EPA is proposing?
II. Fine Particulate Matter and the NAAQS
III. What is EPA's analysis of North Carolina's May 16, 2011, and September 5, 2013, SIP submittals addressing NSR requirements?
  A. North Carolina's SIP Submittal Changes Regarding the 2008 NSR $PM_{2.5}$ Implementation Rule
  B. North Carolina's SIP Submittal Changes Regarding the 2010 PSD $PM_{2.5}$ Rule
  C. North Carolina's Miscellaneous SIP Submittal Changes Regarding the NSR Program
IV. What is EPA's analysis of the PSD elements for North Carolina's infrastructure SIP submittals?
  A. PSD Elements for Infrastructure Submittals for the 2008 Lead, 2008 8-Hour Ozone, 2010 NO_2, 2010 SO_2 and 2012 $PM_{2.5}$ NAAQS
  B. PSD Elements for Infrastructure Submittals for the 1997 and 2006 $PM_{2.5}$ NAAQS
V. Incorporation by Reference
VI. Proposed Actions
VII. Statutory and Executive Order Reviews

I. What are the actions EPA is proposing?

EPA is proposing four actions, some with multiple parts, with regard to North Carolina's SIP submittals updating the State's PSD and NNSR regulations found at 15A North Carolina Administrative Code (NCAC) 02D .0530 and 15A NCAC 02D .0531.[1] First, EPA is proposing to approve a May 16, 2011, SIP submittal from North Carolina (as revised and updated by the State's September 5, 2013, SIP submittal) as meeting the requirements of EPA's rule, "Implementation of the New Source Review (NSR) Program for Particulate Matter Less Than 2.5 Micrometers

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[1] North Carolina's preconstruction permitting program for new and modified stationary sources is codified at 15A NCAC Subchapter 02D. Specifically, North Carolina's PSD preconstruction regulations are found at 15A NCAC 02D .0530 and apply to major stationary sources or modifications constructed in areas designated attainment or unclassifiable/attainment for the NAAQS, as required under part C of title I of the Clean Air Act (CAA or Act). North Carolina's NNSR regulations are found at 15A NCAC 02D .0531 and apply to the construction and modification of any major stationary source of air pollution in or impacting upon a NAAQS nonattainment area, as required by Part D of title I of the CAA.

($PM_{2.5}$);" Final Rule, 73 FR 28321 (May 16, 2008) (hereafter referred to as the "2008 NSR $PM_{2.5}$ Implementation Rule").

Second, EPA is proposing to disapprove North Carolina's September 5, 2013, SIP submittal with regard to changes to the State's regulation at 15A NCAC 02D .0530 because North Carolina's changes do not fully meet the requirements of EPA's rulemaking, "Prevention of Significant Deterioration (PSD) for Particulate Matter Less Than 2.5 Micrometers ($PM_{2.5}$)—Increments, Significant Impact Levels (SILs) and Significant Monitoring Concentration (SMC)," Final Rule, 75 FR 64864 (October 20, 2010) (hereafter referred to as the "2010 PSD $PM_{2.5}$ Rule").

Third, EPA is proposing to approve administrative changes to North Carolina's PSD and NNSR regulations at 15A NCAC 02D .0530 and 15A NCAC 02D .0531 provided by the State in a SIP submittal also dated May 16, 2011, including clarification of the applicability of best available control technology (BACT) and lowest achievable emission rate (LAER) for electrical generating units (EGUs) in the State, and the inclusion of an additional Federal Land Manager (FLM) notification provision.

Lastly, as a result of the proposed disapproval of a portion of the State's NSR requirements, EPA is proposing to approve, in part, and disapprove, in part, the PSD elements of the North Carolina's infrastructure SIP submittals for the 2008 lead, 2008 8-hour ozone, 2010 SO_2, 2010 NO_2 and the 2012 $PM_{2.5}$ NAAQS and to convert the Agency's previous conditional approvals of the PSD elements of the North Carolina's infrastructure SIP submittals for the 1997 Annual $PM_{2.5}$ and 2006 24-hour $PM_{2.5}$ NAAQS to partial approvals and partial disapprovals.

II. Fine Particulate Matter and the NAAQS

"Particulate matter," also known as particle pollution or PM, is a complex mixture of extremely small particles and liquid droplets. Particle pollution is made up of a number of components, including acids (such as nitrates and sulfates), organic chemicals, metals, and soil or dust particles. The size of particles is directly linked to their potential for causing health problems. EPA is concerned about particles that are 10 micrometers in diameter or smaller because those are the particles that generally pass through the throat and nose and enter the lungs. Once inhaled, these particles can affect the heart and lungs and cause serious health effects. EPA groups particle pollution into two categories:

- "Inhalable coarse particles," or PM_{10}, are particles larger than 2.5 micrometers but smaller than 10 micrometers in diameter. Inhalable coarse particles can be directly emitted from sources such as roadways and industries that create dusty emissions.
- "Fine particles," or $PM_{2.5}$, are solid or liquid particles that are 2.5 micrometers in diameter and smaller. Fine particles can be directly emitted from sources such as industrial processes, diesel and gasoline engines, and wildfires, or they can be formed in the atmosphere secondarily as a result of chemical reactions between specific pollutants (known as $PM_{2.5}$ precursors) that are emitted primarily from mobile and stationary combustion sources.

The Clean Air Act (CAA or Act) requires EPA to set air quality standards to protect both public health and the public welfare (*e.g.,* visibility, crops and vegetation). Particle pollution, especially fine particles, affects both. The human health effects associated with long- or short-term exposure to $PM_{2.5}$ are significant and include premature mortality, aggravation of respiratory and cardiovascular disease (as indicated by increased hospital admissions and emergency room visits) and development of chronic respiratory disease. In addition, welfare effects associated with elevated $PM_{2.5}$ levels include visibility impairment as well as effects on sensitive ecosystems, materials damage and soiling and climatic and radiative processes.

On July 18, 1997, EPA revised the NAAQS for PM to add new standards for fine particles, using $PM_{2.5}$ as the indicator. *See* 62 FR 38652. Previously, EPA used PM_{10} (inhalable particles smaller than or equal to 10 micrometers in diameter) as the indicator for the PM NAAQS. EPA established health-based (primary) annual and 24-hour standards for $PM_{2.5}$, setting an annual standard at a level of 15 micrograms per cubic meter ($\mu g/m^3$) and a 24-hour standards at a level of 65 $\mu g/m^3$. *Id.* At the time EPA established the 1997 primary standards, EPA also established welfare-based (secondary) standards identical to the primary standards. *Id.* The secondary standards are designed to protect against major environmental effects of $PM_{2.5}$, such as visibility, impairment, soiling, and materials damage. *Id.* On October 17, 2006, EPA revised the primary and secondary NAAQS for $PM_{2.5}$. *See* 71 FR 61236. In that rulemaking, EPA reduced the 24-hour NAAQS for $PM_{2.5}$ to 35 $\mu g/m^3$ and retained the existing annual $PM_{2.5}$ NAAQS of 15 $\mu g/m^3$. *Id.* On December 14, 2012, the EPA Administrator signed a final rule revising the annual $PM_{2.5}$ NAAQS to 12 $\mu g/m^3$. *See* 78 FR 3086 (January 15, 2013).

Whenever a new or revised NAAQS is promulgated, section 110(a) of the CAA obligates states to submit SIP revisions that provide for the implementation, maintenance, and enforcement of the new or revised NAAQS within three years following promulgation of such NAAQS—the so-called infrastructure SIP revisions. Although states typically have met many of the basic program elements required in section 110(a)(2) through earlier SIP submittals in connection with previous PM standards, states were still required to submit SIP revisions that address section 110(a)(2) for the 1997, 2006 and 2012 $PM_{2.5}$ NAAQS.

III. What is EPA's analysis of North Carolina's May 16, 2011, and September 5, 2013, SIP submittals addressing NSR requirements?

North Carolina provided its May 16, 2011, and September 5, 2013, SIP submittals to, among other things, comply with federal permitting requirements related to implementation of the $PM_{2.5}$ NAAQS through the NSR program. The relevant federal $PM_{2.5}$ permitting requirements for SIPs, set forth in 40 CFR 51.165 and 51.166, were promulgated by EPA in the 2008 NSR $PM_{2.5}$ Implementation Rule and the 2010 PSD $PM_{2.5}$ Rule. States were required to make their SIP submittals to address the requirements of the 2008 NSR $PM_{2.5}$ Implementation Rule no later than May 16, 2011, and to make their submittals to address the requirements of the 2010 PSD $PM_{2.5}$ Rule no later than July 20, 2012.

A. North Carolina's SIP Submittal Changes Regarding the 2008 NSR $PM_{2.5}$ Implementation Rule

North Carolina submitted its SIP to comply with the requirements of the 2008 NSR $PM_{2.5}$ Implementation Rule on May 16, 2011. Subsequently, on September 5, 2013, North Carolina submitted an update to its original submittal to correct a deficiency related to the significant emission rate for nitrogen oxides (NO_X) as a precursor to $PM_{2.5}$ formation. Background on the 2008 NSR $PM_{2.5}$ Implementation Rule and EPA's analysis of North Carolina's SIP submittals to comply with that rule is provided below.

1. Background on EPA's 2008 NSR $PM_{2.5}$ Implementation Rule

On May 16, 2008, EPA finalized the 2008 NSR $PM_{2.5}$ Rule to implement the 1997 $PM_{2.5}$ NAAQS for the NSR permitting program. *See* 73 FR 28321. The 2008 NSR $PM_{2.5}$ Implementation Rule revised the federal NSR program requirements to establish the framework for implementing preconstruction permit review for the $PM_{2.5}$ NAAQS in both attainment and nonattainment areas. Among other things, the 2008 NSR $PM_{2.5}$ Rule required states to incorporate into their SIPs the following components of the NSR program for the $PM_{2.5}$ NAAQS: (1) The requirement for NSR permits to address directly emitted $PM_{2.5}$ and precursor pollutants that contribute to the secondary formation of $PM_{2.5}$; (2) significant emission rates for direct $PM_{2.5}$ and precursor pollutants that lead to the secondary formation of $PM_{2.5}$ (including SO_2, NO_X, and volatile organic compounds (VOC)[2]); (3) NNSR $PM_{2.5}$ emission offsets; and (4) the requirement for applicability determinations and emission limits in PSD and NNSR permits to account for gases that condense to form particles (condensables) in $PM_{2.5}$ and PM_{10}.[3]

North Carolina's May 16, 2011, SIP submittal (as revised by the State's September 5, 2013, SIP submittal) addresses the PSD and NNSR provisions established in EPA's May 16, 2008, NSR $PM_{2.5}$ Implementation Rule. Two key issues, the NSR $PM_{2.5}$ litigation and condensable particulate matter emissions, are described in greater detail below.

a. NSR $PM_{2.5}$ Litigation

On January 4, 2013, the United States Court of Appeals for the District of Columbia Circuit (hereafter referred to as the DC Circuit or Court) issued a judgment[4] that remanded two of EPA's rules promulgated for implementation of the 1997 $PM_{2.5}$ NAAQS, including the 2008 NSR $PM_{2.5}$ Implementation Rule. *See Natural Resources Defense Council* v. *EPA,* 706 F.3d 428 (D.C. Cir. 2013). The Court found that EPA erred in implementing the $PM_{2.5}$ NAAQS in these rules solely pursuant to the general implementation provisions of subpart 1 of part D of title I of the CAA, rather than pursuant to the additional implementation provisions specific to particulate matter nonattainment areas in subpart 4. EPA had developed the NNSR requirements in the 2008 NSR $PM_{2.5}$ Implementation Rule pursuant to the general nonattainment requirements of subpart 1 of Part D, title I, of the CAA. Relative to subpart 1, subpart 4 of Part D, title I includes additional provisions that apply to PM_{10} nonattainment and is more specific about what states must do to bring areas into attainment. In particular, subpart 4 includes section 189(e) of the CAA, which requires the control of major stationary sources of PM_{10} precursors (and hence under the court decision, $PM_{2.5}$ precursors) "except where the Administrator determines that such sources do not contribute significantly to PM_{10} levels which exceed the standard in the area." The Court found that subpart 4 applies to $PM_{2.5}$ nonattainment and ordered EPA to repromulgate the 2008 $PM_{2.5}$ Implementation Rule pursuant to subpart 4.

The 2008 NSR $PM_{2.5}$ Implementation Rule promulgated new NSR requirements for implementation of $PM_{2.5}$ in both nonattainment areas (NNSR) and attainment/unclassifiable areas (PSD). As Subpart 4 includes requirements only pertinent to nonattainment areas, EPA does not consider the portions of the 2008 rule that address requirements for $PM_{2.5}$ attainment and unclassifiable areas to be affected by the Court's opinion.

On June 2, 2014, EPA published a final rule[5] which, in part, set a December 31, 2014, deadline for states to make any remaining required SIP submittals needed for an attainment plan or the NNSR program, pursuant to and considering the application of subpart 4. *See* 79 FR 31566. Requirements under subpart 4 for a moderate nonattainment area are generally comparable to subpart 1, including: (1) CAA section 189(a)(1)(A) (NNSR permit program); (2) section 189(a)(1)(B) (attainment demonstration or demonstration that attainment by the applicable attainment date is impracticable); (3) section 189(a)(1)(C) (reasonably available control measures and reasonably available control technology; and (4) section 189(c) (reasonable further progress and quantitative milestones). The additional requirements pursuant to subpart 4 as opposed to subpart 1 correspond to section 189(e) (precursor requirements for major stationary sources). Further additional SIP planning requirements are introduced by subpart 4 in the event that a moderate nonattainment area is reclassified to a serious nonattainment area, or in the event that the moderate nonattainment area needs additional time to attain the NAAQS. The additional requirements under subpart 4 are not applicable for the purposes of CAA section 107(d)(3)(E) in any area that has submitted a complete redesignation request prior to the due date for those requirements; therefore, EPA is not required to consider subpart 4 requirements for moderate nonattainment areas that have submitted a redesignation request prior to December 31, 2014, or for any area that has already been redesignated to attainment. *See* 79 FR at 31570.

Two areas were initially designated nonattainment for the 1997 Annual $PM_{2.5}$ NAAQS in North Carolina: The Greensboro-Winston Salem-High Point Area (hereafter referred to as the Greensboro Area)[6] and the Hickory-Morganton-Lenoir Area (hereafter referred to as the Hickory Area).[7] On December 18, 2009 (later supplemented on December 22, 2010), NC DEQ[8] submitted redesignation requests for the Greensboro Area and the Hickory Area. These requests were granted, and the Greensboro Area and the Hickory Area were both redesignated to attainment on November 18, 2011. *See* 76 FR 71455 and 76 FR 71452, respectively. Because the counties comprising these areas have been redesignated to attainment, and no portions of North Carolina were designated nonattainment for either the 2006 $PM_{2.5}$ NAAQS or the 2012 $PM_{2.5}$ NAAQS, the State has no existing $PM_{2.5}$ nonattainment areas. Therefore, the State is not currently required to regulate $PM_{2.5}$ as part of its NNSR permitting program and, accordingly, the State did not need to submit additional SIP elements for $PM_{2.5}$ to satisfy the Subpart 4 requirements.

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[2] Under the 2008 NSR $PM_{2.5}$ Rule, VOC is presumed not to be a precursor to $PM_{2.5}$ unless the state demonstrates to the Administrator's satisfaction or EPA demonstrates that emissions of VOC from sources in a specific area are a significant contributor to that area's ambient $PM_{2.5}$ concentrations.

[3] Additionally, the 2008 NSR $PM_{2.5}$ Implementation Rule authorized states to adopt provisions in their nonattainment NSR rules that allowed for "interpollutant trading" for emission offsets. Specifically, the rule authorized states to allow new major stationary sources and major modifications in $PM_{2.5}$ nonattainment areas to offset increases of direct $PM_{2.5}$ emissions or $PM_{2.5}$ precursors with reductions of either direct $PM_{2.5}$ emissions or $PM_{2.5}$ precursors in accordance with interpollutant offset ratios contained in the area's approved SIP. North Carolina elected not to include interpollutant trading ratios in its final SIP submittals and therefore will not be implementing interpollutant trading at this time.

[4] The Natural Resources Defense Council, Sierra Club, American Lung Association, and Medical Advocates for Healthy Air challenged before the DC Circuit EPA's April 25, 2007, Rule entitled "Clean Air Fine Particle Implementation Rule," 72 FR 20586, which established detailed implementation regulations to assist states with the development of SIPs to demonstrate attainment for the 1997 Annual and 24-hour $PM_{2.5}$ NAAQS and the separate May 16, 2008, NSR $PM_{2.5}$ Implementation Rule (which is considered in this proposed rulemaking). This proposed rulemaking only pertains to the impacts of the Court's decision on the May 16, 2008, NSR $PM_{2.5}$ Implementation Rule.

[5] The rule is titled "Identification of Nonattainment Classification and Deadlines for Submission of State Implementation Plan (SIP) Provisions for the 1997 Fine Particle ($PM_{2.5}$) National Ambient Air Quality Standard (NAAQS) and 2006 $PM_{2.5}$ NAAQS," Final Rule, 79 FR 31566 (June 2, 2014). This final rule also identifies the initial classification of current 1997 and 2006 $PM_{2.5}$ nonattainment areas as moderate and the EPA guidance and relevant rulemakings that are currently available regarding implementation of subpart 4 requirements.

[6] The nonattainment area for the Greensboro Area for the 1997 $PM_{2.5}$ standard was comprised of Guilford and Davidson counties.

[7] The nonattainment area for the Hickory Area for the 1997 $PM_{2.5}$ standard was comprised of Catawba County only.

[8] Formerly the North Carolina Department of Environment and Natural Resources.

b. Condensables

In the 2008 NSR $PM_{2.5}$ Rule, EPA revised the definition of "regulated NSR pollutant" for PSD by adding paragraph 51.166(b)(49)(vi), which provided that "particulate matter (PM) emissions, $PM_{2.5}$ emissions and PM_{10} emissions" shall include gaseous emissions from a source or activity which condense to form PM at ambient temperatures and that on or after January 1, 2011, such condensable PM shall be accounted for in applicability determinations and in establishing emissions limitations for PM, $PM_{2.5}$ and PM_{10} in permits. *See* 73 FR at 28335. A similar paragraph revised the definition of "regulated NSR pollutant" in the NNSR rule but specified applicability to only "$PM_{2.5}$ emissions and PM_{10} emissions" and not to "particulate matter (PM) emissions." *See* 40 CFR 51.165(a)(1)(xxxvii)(D).

Subsequently, EPA concluded that the 2008 NSR $PM_{2.5}$ Rule's requirement that the measurement of "particulate matter emissions" (as opposed to $PM_{2.5}$ or PM_{10}) must include the condensable fraction of primary PM was an inadvertent error. On October 25, 2012, EPA corrected this inadvertent error by revising the definition of "regulated NSR pollutant" contained in the regulations for PSD at 40 CFR 51.166 and 52.21, and in EPA's Emission Offset Interpretative Ruling at 40 CFR part 51 Appendix S. *See* 77 FR 65107. In taking that action, EPA explained that requiring inclusion of condensable PM in measurements of "particulate matter emissions" would have little if any effect on preventing significant air quality deterioration or on efforts to attain the primary and secondary PM NAAQS. *See* 77 FR at 65112. Thus, as revised, the federal PSD regulations do not require the inclusion of condensable PM in measurements of "particulate matter emissions," except where either the applicable NSPS compliance test includes the condensable PM fraction or the applicable implementation plan requires the condensable PM fraction to be counted. *Id.*

North Carolina's May 16, 2011, SIP submittal (as updated by the September 5, 2013, submittal) adopts EPA's definition for "regulated NSR pollutant" requiring states to consider condensables (at 40 CFR 51.166(b)(49)(vi)). However, because the State's submittal adopts the definitions in the CFR as of May 16, 2008 (prior to EPA's correction), the State's rule requires sources to account for the condensable fraction in the measurement and regulation of "PM emissions" as well as "$PM_{2.5}$ emissions" and "PM_{10} emissions." As explained above, this difference between North Carolina's regulations and the current federal PSD regulations does not impact North Carolina's efforts to prevent significant deterioration of air quality or to attain and maintain compliance with the PM NAAQS.

2. EPA's Analysis of North Carolina's SIP Submittal Changes Regarding the 2008 NSR $PM_{2.5}$ Implementation Rule

In a May 16, 2011, SIP submittal intended to satisfy the State's obligations under the 2008 $PM_{2.5}$ Implementation Rule, North Carolina proposed to incorporate by reference (IBR) into North Carolina's SIP, with one exception, the relevant portions of the federal PSD and NNSR permitting regulations at 40 CFR 51.166 and 51.165 effective as of May 16, 2008.[9] Specifically, North Carolina's May 16, 2011, submittal incorporates by reference into North Carolina's PSD regulations at 15A NCAC 02D .0530 (state effective date January 2, 2011) and into North Carolina's NNSR regulations at 15A NCAC 02D .0531 (state effective date January 2, 2011) the following PSD and NNSR provisions promulgated in the 2008 NSR $PM_{2.5}$ Implementation Rule: (1) The requirement for PSD and NNSR permits to address directly emitted $PM_{2.5}$ and precursor pollutants (SO_2 and NO_X (as codified at 40 CFR 51.165(a)(1)(xxxvii)(C) and 51.166(b)(49)); (2) the significant emission rates for direct $PM_{2.5}$ and precursor pollutant (SO_2) (as codified at 40 CFR 51.165(a)(1)(x)(A) and 51.166(b)(23)(i)); (3) the NNSR $PM_{2.5}$ emission offsets (as codified at 51.165(9)(i)); and (4) the PSD and NNSR requirement that condensable PM, PM_{10} and $PM_{2.5}$ emissions be accounted in PSD applicability determinations and in establishing emissions limitations for permitting (as codified at 40 CFR 51.165(a)(1)(xxxvii)(D) and 51.166(b)(49)).[10]

The one exception to North Carolina's IBR of relevant requirements from the 2008 NSR $PM_{2.5}$ Implementation Rule in the State's May 16, 2011, submittal is the significant emissions rate for NO_X as a precursor to the secondary formation of $PM_{2.5}$. Specifically, instead of incorporating the 40 tons per year (tpy) significant emission rate for NO_X as a $PM_{2.5}$ precursor (set forth at 40 CFR 51.165(a)(1)(x)(A) and 40 CFR 51.166(b)(23)(i)), the state regulations included in North Carolina's May 16, 2011, SIP submittal set the rate at 140 tpy for both PSD and NNSR (at 15A NCAC 02D .0530(b)(4) and 15A NCAC 02D .0531(a)(3)).

As mentioned above, in the 2008 NSR $PM_{2.5}$ Rule, EPA promulgated final rules governing the implementation of NSR program for $PM_{2.5}$ including adding significant emission rates for direct $PM_{2.5}$ and their precursors of SO_2 and NO_X. EPA's permitting program uses significant emission rates to determine the applicability of major NSR requirements to existing sources undergoing modifications. Specifically, EPA established the federal definition of "significant" for $PM_{2.5}$ is 40 tpy for NO_X unless it is demonstrated not to be a $PM_{2.5}$ precursor as provided under the definition of "Regulated NSR Pollutant." *See* 40 CFR 51.165(a)(1)(x)(A) and 51.166(b)(23)(i). Pursuant to 40 CFR 51.166, a SIP can be more stringent than required by 40 CFR 51.166 but not less stringent. Under the 2008 NSR $PM_{2.5}$ Implementation Rule, unless the state demonstrates that NO_X is not a significant contributor to $PM_{2.5}$ in a specific area, the significance threshold for NO_X as a $PM_{2.5}$ precursor can be no higher than 40 tpy. 40 CFR 51.166(b)(23)(i). North Carolina did not submit a demonstration that NO_X is not a significant contributor to $PM_{2.5}$ formation in the State. Thus, North Carolina's adoption of a significant emission rate of 140 tpy for NO_X as a precursor to $PM_{2.5}$ in its May 16, 2011, SIP submittal is inconsistent with the federal requirements.

In a subsequent SIP submittal, dated September 5, 2013, North Carolina revised the significant emission rate for NO_X as a $PM_{2.5}$ precursor. Specifically, North Carolina submitted updated versions of 15A NCAC 02D .0530 (state effective date September 1, 2013) and 15A NCAC 02D .0531 (state effective date September 1, 2013) that IBR the federal rate of 40 tpy for NO_X as a $PM_{2.5}$ precursor into the North Carolina. *See* 15A NCAC 02D .0530(b)(4) (PSD regulations) and 15A NCAC 02D .0531(a)(3) (NNSR regulations). Therefore, the 140 tpy significant emission rate for NO_X as a $PM_{2.5}$ precursor originally proposed in North Carolina's May 16, 2008, SIP submittal has been replaced and is no longer before the Agency for review and consideration.

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[9] Paragraph (w) of 15A NCAC 02D .0530 (effective date January 2, 2011) and Paragraph (o) of 15A NCAC 02D .0531 (effective date January 2, 2011) states: "The reference to the Code of Federal Regulations (CFR) in this Rule are incorporated by reference unless a specific reference states otherwise. Except for 40 CFR 81.334, the version of the CFR incorporated in this Rule is that as of May 16, 2008, and does not include any subsequent amendments or editions to the referenced material."

[10] As discussed above, on October 25, 2012, EPA removed the requirement that condensable PM be included in measurements of "particulate matter emissions." *See* 77 FR 65107.

EPA notes that North Carolina's submittal contains provisions relevant to nonattainment NSR programs for $PM_{2.5}$ nonattainment areas. Specifically, in the definition of "regulated NSR pollutant," the submittal provides that SO_2 is a $PM_{2.5}$ precursor, NO_X is presumed to be a $PM_{2.5}$ precursor, and VOCs and ammonia are presumed to not be $PM_{2.5}$ precursors. This provision is consistent with the nonattainment NSR regulations promulgated in the 2008 $PM_{2.5}$ NSR Implementation Rule. However, as mentioned above, on January 4, 2013, the DC Circuit, in *Natural Resources Defense Council* v. *EPA,* 706 F.3d at 428, issued a decision that remanded the 2008 $PM_{2.5}$ NSR Implementation Rule back to EPA. The Court held that the provisions of subpart 4 of the CAA apply in areas designated nonattainment for a $PM_{2.5}$ NAAQS. These subpart 4 requirements, as applied to $PM_{2.5}$, include section 189(e) of the CAA, which requires the control of major stationary sources of $PM_{2.5}$ and all $PM_{2.5}$ precursors, *i.e.,* SO_2, NO_X, VOC, and ammonia, in $PM_{2.5}$ nonattainment areas unless the Administrator determines that such sources of a particular precursor do not contribute significantly to levels that exceed the standard in the nonattainment area.

Although the State's submittal only requires regulation of SO_2 and NO_X as $PM_{2.5}$ precursors in its NNSR permitting program, the State of North Carolina has no $PM_{2.5}$ nonattainment areas. Accordingly, EPA finds it reasonable to conclude that major sources of VOCs and ammonia currently do not contribute significantly to $PM_{2.5}$ nonattainment within the State. Thus, there is no need at this time for the State to regulate VOCs or ammonia as $PM_{2.5}$ precursors in the State's nonattainment NSR permitting program, and this issue does not prevent EPA from approving the $PM_{2.5}$ precursor provisions in North Carolina's May 16, 2011, SIP submittal (as revised by the State's September 5, 2013 submittal). Should EPA in the future designate an area in North Carolina as nonattainment for $PM_{2.5}$, the State would have the obligation to submit a SIP revision demonstrating that the nonattainment NSR program meets all applicable requirements for $PM_{2.5}$, including appropriate control of major sources of $PM_{2.5}$ precursors under 189(e). *See* CAA sections 172(c)(5) and 189(a)(1)(A), (2)(B).

EPA has preliminarily determined that North Carolina's May 16, 2011, SIP submittal, as updated by the September 5, 2013 SIP submittal, satisfies the requirements of the 2008 NSR $PM_{2.5}$ Implementation Rule. Consequently, EPA is proposing to approve North Carolina's submittal (as updated) and to incorporate 15A NCAC 02D .0530 (state effective date September 1, 2013) and 15A NCAC 02D .0531 (state effective date September 1, 2013) into North Carolina's SIP, with the exception of certain regulatory provisions identified and discussed below.

B. North Carolina's SIP Submittal Changes Regarding the 2010 PSD $PM_{2.5}$ Rule

North Carolina submitted its SIP to comply with the 2010 PSD $PM_{2.5}$ Rule on September 5, 2013. Background on the 2010 PSD $PM_{2.5}$ Rule and EPA's analysis of North Carolina's SIP submittal to comply with that rule is provided below.

1. Background on EPA's 2010 PSD $PM_{2.5}$ Rule

a. Requirements of the 2010 PSD $PM_{2.5}$ Rule for PSD SIP Programs

EPA finalized the 2010 PSD $PM_{2.5}$ Rule to provide additional regulatory requirements under the PSD SIP program regarding the implementation of the $PM_{2.5}$ NAAQS. *See* 75 FR at 64864. The 2010 PSD $PM_{2.5}$ Rule required states to submit SIP revisions to EPA by July 20, 2012, adopting provisions equivalent to or at least as stringent as the PSD increments and associated implementing regulations. Specifically, the 2010 PSD $PM_{2.5}$ Rule requires states to adopt and submit for EPA approval into their SIP the numerical $PM_{2.5}$ increments promulgated pursuant to section 166(a) of the CAA to prevent significant deterioration of air quality in areas meeting the NAAQS. States are also required to adopt and submit for EPA approval revisions to the definitions for "major source baseline date," "minor source baseline date," and "baseline area" as part of the implementing regulations for the $PM_{2.5}$ increment.[11]

b. Requirement for $PM_{2.5}$ Increments

As established in part C of title I of the CAA, EPA's PSD program protects public health from adverse effects of air pollution by ensuring that construction of new major sources or modifications in attainment or unclassifiable areas does not lead to significant deterioration of air quality while simultaneously ensuring that economic growth will occur in a manner consistent with preservation of clean air resources. Under section 165(a)(3) of the CAA, a PSD permit applicant must demonstrate that emissions from the proposed construction and operation of a facility "will not cause, or contribute to, air pollution in excess of any maximum allowable increase or allowable concentration for any pollutant." In other words, when a source applies for a permit to emit a regulated pollutant in an area that is designated as attainment or unclassifiable for a NAAQS, the state and EPA must determine if emissions of the regulated pollutant from the source will cause significant deterioration in air quality. Significant deterioration occurs when the amount of the new pollution exceeds the applicable PSD increment, which is the "maximum allowable increase" of an air pollutant allowed to occur above the applicable baseline concentration[12] for that pollutant. Therefore, an increment is the mechanism used to estimate "significant deterioration" of air quality for a pollutant in an area.

For purposes of calculating increment consumption, a baseline area for a particular pollutant includes the attainment or unclassifiable area in which the source is located, as well as any other attainment or unclassifiable area in which the source's emissions of that pollutant are projected (by air quality modeling) to result in a significant ambient pollutant increase. *See* 40 CFR 51.166(b)(14)(ii). Once the baseline area is established, subsequent PSD sources locating in that area need to consider that a portion of the available increment may have already been consumed by previous emissions increases.

In general, the submittal date of the first complete PSD permit application in a particular area is the operative "baseline date" after which new sources must evaluate increment consumption.[13] On or before the date of the first complete PSD application, emissions generally are considered to be part of the baseline concentration from which increment consumption is calculated, except for certain changes in emissions from major stationary sources. Emissions increases that occur after the baseline date will be counted toward the amount of increment consumed. Similarly, emissions decreases after the applicable baseline date restore or expand the amount of increment that is available.

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[11] The 2010 PSD $PM_{2.5}$ Rule also gave states discretion to adopt $PM_{2.5}$ SILs and a SMC. *See* 75 FR at 64900. On January 22, 2013, the DC Circuit vacated and remanded to EPA the portions of 50 CFR 51.166 and 52.21 addressing the $PM_{2.5}$ SILs and also vacated the parts of the rule that established the $PM_{2.5}$ SMC. North Carolina's September 5, 2013, submittal does not include SILs or SMC so these regulatory provisions are not relevant to today's proposed action.

[12] Section 169(4) of the CAA provides that the baseline concentration of a pollutant for a particular baseline area is generally the air quality at the time of the first application for a PSD permit in the area.

In practice, three dates related to the PSD baseline concept are important in understanding how to calculate the amount of increment consumed—(1) trigger date; (2) major source baseline date; and (3) minor source baseline date. The first relevant date is the trigger date. The trigger date, as the name implies, is a fixed date that triggers the overall increment consumption process nationwide. *See* 40 CFR 51.166(b)(14)(ii). The two remaining dates—"major source baseline date" and "minor source baseline date"—are necessary to properly account for the emissions that are to be counted toward the amount of increment consumed following the national trigger date, in accordance with the statutory definition of "baseline concentration" in section 169(4) of the Act. The "major source baseline date," which precedes the trigger date, is the date after which actual changes in emissions associated with construction at any major stationary source affect the PSD increment. Such changes in emissions are not included in the baseline concentration, even if the changes in emissions occur before the minor source baseline date. In accordance with the statutory definition of "baseline concentration" at section 169(4), the PSD regulations define a fixed date to represent the major source baseline date for each pollutant for which an increment exists. The "minor source baseline date" is the earliest date after the trigger date on which a source or modification submits the first complete application for a PSD permit in a particular area. This is the date on which the baseline concentration is generally established. After the minor source baseline date, any change in actual emissions (from both major and minor sources) affects the PSD increment for that area.

Once the minor source baseline date is established, the new emissions increase from the major source submitting the first PSD application consumes a portion of the increment in that area, as do any subsequent actual emissions increases that occur from any new or existing source in the area. When the maximum pollutant concentration increase defined by the increment has been reached, additional PSD permits cannot be issued until sufficient amounts of the increment are "freed up" via emissions reductions that may occur voluntarily (*e.g.*, via source shutdowns) or by mandatory control requirements imposed by the reviewing authority. Moreover, the air quality in a region cannot deteriorate to a level in excess of the applicable NAAQS, even if all the increment in the area has not been consumed. Therefore, new or modified sources located in areas where the air pollutant concentrations are near the level allowed by the NAAQS may not have full use of the amount of pollutant concentration increase allowed by the increment.

In the 2010 PSD $PM_{2.5}$ Rule, pursuant to the authority under section 166(a) of the CAA, EPA promulgated numerical increments for $PM_{2.5}$ as a new pollutant[14] for which NAAQS were established after August 7, 1977,[15] and derived 24-hour and annual $PM_{2.5}$ increments for the three area classifications (Class I, II and III). *See* 75 FR at 64869 and the ambient air increment table at 40 CFR 51.166(c)(1). EPA also established the $PM_{2.5}$ "trigger date" as October 20, 2011 (40 CFR 51.166(b)(14)(ii)(c)), and the $PM_{2.5}$ "major source baseline date" as October 20, 2010 (40 CFR 51.166(b)(14)(i). *See* 75 FR at 64903. Finally, EPA amended the term "baseline area" at 40 CFR 51.166(b)(15)(i) to include a level of significance of 0.3 µg/m^3, annual average, for establishing a new baseline area for purposes of $PM_{2.5}$ increments. *Id.*

2. EPA's Analysis of North Carolina's SIP Submittal Changes Regarding the 2010 PSD $PM_{2.5}$ Rule

North Carolina's September 5, 2013, SIP submittal adopts into the State's PSD permitting program at 15A NCAC 02D .0530 changes purporting to meet the requirements for $PM_{2.5}$ increments in EPA's 2010 PSD $PM_{2.5}$ Rule. However, while North Carolina's revised PSD regulations incorporate the numerical $PM_{2.5}$ increments at paragraphs (q) and (v) of 15A NCAC 02D .0530, the regulations do not include other key regulatory provisions needed to implement the $PM_{2.5}$ increments in accordance with federal requirements. Specifically, North Carolina's changes to 15A NCAC 02D .0530 fail to incorporate the following federal requirements pertaining to implementation of $PM_{2.5}$ increments: (1) the definition of "[m]ajor source baseline date" for $PM_{2.5}$ codified at 40 CFR 51.166(b)(14)(i)(c) (defined as October 20, 2010); (2) the definition of "[m]inor source baseline date" for $PM_{2.5}$ codified at 40 CFR 51.166(b)(14)(ii)(c) (which establishes the $PM_{2.5}$ trigger date as October 20, 2011); and (3) the definition of "[b]aseline area" codified at 40 CFR 51.166(b)(15)(i).[16]

Without the federally required definitions of "major source baseline date," "minor source baseline date," and "baseline area" set forth in the 2010 PSD $PM_{2.5}$ Rule, North Carolina's PSD regulations do not require PSD sources to conduct the appropriate analyses demonstrating that emissions from proposed construction of major sources or modifications will not cause or contribute to air pollution beyond the $PM_{2.5}$ increment. While a State has the option of demonstrating that it has alternative measures in its plan other than the $PM_{2.5}$ increment requirements that satisfy the prevention of significant deterioration requirements under sections 166(c) and 166(d) of the CAA (*see* 40 CFR 51.166(c)(2)), North Carolina did not offer any such demonstration in connection with its September 5, 2013, SIP submittal. Therefore, EPA proposes to disapprove the portion of North Carolina's September 5, 2013, SIP submittal pertaining to adoption and implementation of the $PM_{2.5}$ PSD increments on the basis that, taken as a whole, they are insufficient to satisfy the federal $PM_{2.5}$ PSD increment requirements set forth in the 2010 PSD $PM_{2.5}$ Rule. Specifically, EPA proposes to disapprove the changes to 15A NCAC 02D .0530, paragraphs (e), (q), and (v) that pertain to the $PM_{2.5}$ increments.[17] EPA notes that while the numerical $PM_{2.5}$ increments at paragraphs (q) and (v) correctly reflect the numerical $PM_{2.5}$ increments required by EPA's 2010 PSD $PM_{2.5}$ Rule, EPA proposes to disapprove these provisions because North Carolina cannot properly apply the $PM_{2.5}$ increments without adopting the associated definitions of "major source baseline date," "minor source baseline date," and "baseline area."

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[13] Baseline dates are pollutant-specific. That is, a complete PSD application establishes the baseline date only for those regulated NSR pollutants that are projected to be emitted in significant amounts (as defined in the regulations) by the applicant's new source or modification. Thus, an area may have different baseline dates for different pollutants.

[14] EPA generally characterized the $PM_{2.5}$ NAAQS as a NAAQS for a new indicator of PM. EPA did not replace the PM_{10} NAAQS with the NAAQS for $PM_{2.5}$ when the $PM_{2.5}$ NAAQS were promulgated in 1997. EPA rather retained the Annual and 24-hour NAAQS for PM_{10} (retaining PM_{10} as an indicator of coarse particulate matter) and treated $PM_{2.5}$ as a new pollutant for purposes of developing increments. *See* 75 FR at 64864.

[15] EPA interprets section 166(a) to authorize EPA to promulgate pollutant-specific PSD regulations meeting the requirements of section 166(c) and 166(d) for any pollutant for which EPA promulgates a NAAQS after 1977.

[16] North Carolina's draft revisions to 15A NCAC 02D .0530 would have used incorporation by reference (IBR) to adopt the federal regulations in the CFR as of October 20, 2010. In the final regulations, however, North Carolina chose to retain the former IBR date of May 16, 2008. North Carolina also chose in the final regulations to incorporate the numerical $PM_{2.5}$ increments directly into the text of 15A NCAC 02D .0530 rather than to incorporate the increments by reference. However, North Carolina's decision to IBR the provisions in the 2008 CFR rather than the provisions in the 2010 CFR meant that North Carolina did not adopt into its regulations the definitions of "major source baseline," "minor source baseline," and "baseline area" that EPA promulgated in the 2010 PSD $PM_{2.5}$ rule. Rather, North Carolina adopted the definition of these terms as they appeared in the version of the CFR in effect as of May 16, 2008. Thus, the definition of "major source baseline date" incorporated into 15A NCAC 02D .0530 does not include the federally required $PM_{2.5}$ major source baseline date of October 20, 2010, but instead states: "In the case of particulate matter and sulfur dioxide, January 6, 1975." Likewise, the definition of "minor source baseline date" incorporated into 15A NCAC 02D .0530 does not include the federally required $PM_{2.5}$ trigger date of October 20, 2011, but instead states: "In the case of particulate matter and sulfur dioxide, August 7, 1977." It is EPA's understanding that North Carolina interprets the term "particulate matter" in these definitions to encompass $PM_{2.5}$.

C. North Carolina's Miscellaneous SIP Submittal Changes Regarding the NSR Program

In addition to providing SIP submittals to comply with the 2008 NSR $PM_{2.5}$ Implementation Rule and 2010 PSD $PM_{2.5}$ Rule, North Carolina provided administrative changes in the second of two May 16, 2011, SIP submittals (henceforth, the second May 16, 2011, SIP submittal) and in the September 5, 2013, SIP submittal, for the State's NSR regulations at 15A NCAC 02D .0530 (PSD) and 15A NCAC 02D .0531 (NNSR). First, North Carolina's second May 16, 2011, SIP submittal makes changes to clarify that BACT for PSD and LAER for NSR applies to all new natural gas-fired EGUs for which cost recovery is sought under the State's Clean Smokestacks Act (CSA). North Carolina's intended purpose for the rule clarification is to ensure that new-natural gas-fired EGUs that claim cost recovery pursuant to the CSA will not utilize the emission reductions to avoid BACT or LAER under the PSD or NNSR programs, respectively. EPA is proposing to approve this change to North Carolina's SIP for both rules 15A NCAC 02D .0530 and 15A NCAC 02D .0531.

Second, North Carolina's second May 16, 2011, SIP submittal revises 15A NCAC 02D .0531(c) by removing out-of-date, pollutant-specific nonattainment area references (for ozone and carbon monoxide) in the State,[18] and instead proposes to rely on the geographical nonattainment descriptions codified at 40 CFR 81.334 to promptly and accurately identify which areas in the State (for all NAAQS) are designated nonattainment, and thus are subject to NNSR permitting regulations. This change establishes these requirements for all future designated nonattainment areas. By relying on the automatic updates from changes to 40 CFR 81.334, this change would prevent any regulatory confusion and potential SIP gaps for identifying current nonattainment in the State subject to NNSR. EPA is proposing to approve this change as it is consistent with the CAA and EPA's requirements for NNSR.

Third, North Carolina's second May 16, 2011, SIP submittal requests removal of language at 15A NCAC 02D .0531(n), which references text being deleted from 15A NCAC 02D .0531(c), as discussed above, and provides that certain permitting requirements for new major stationary sources or modifications of VOC and NO_X emissions do not apply to sources that can demonstrate through urban airshed modeling that they would not contribute to a violation of the ozone NAAQS. The applicable time period for this provision is between the notification in the *North Carolina Register* of an ozone NAAQS violation in certain area(s) of the State and the designation of such area(s) as nonattainment in 40 CFR 81.334. However, because 15A NCAC 02D .0531(c) is being revised to rely solely on the nonattainment area designations codified at 40 CFR 81.334 and not on the State's notification of ozone NAAQS violations, the language at 15A NCAC 02D .0531(n) will be obsolete. EPA is proposing to approve this change.

Fourth, North Carolina's second May 16, 2011, SIP submittal revises language at 15A NCAC 02D .0530(t) and 15A NCAC 02D .0531(m) regarding notification and administrative requirements related to visibility impacts to Class I Areas from proposed new modified sources. Specifically, North Carolina's revised regulations generally require that the state must notify the Federal Land Managers (FLM) no later than 60 days after receipt of a permit application submitted pursuant to 15A NCAC 02D .0530 (PSD) or 15A NCAC 02D .0531 (NNSR). This 60-day notice requirement is in addition to the pre-existing requirement in North Carolina's SIP-approved PSD and NNSR regulations that the state notify the FLM of any proposed new source or modification that may affect visibility in a Class I area and provide the FLM with "a copy of all information relevant to the permit application including an analysis provided by the source of the potential impact of the proposed source on visibility." *See* 15A NCAC 02D .0530(t)(2) (PSD); 15A NCAC 02D .0531(m)(3) (NNSR).

North Carolina's FLM notification provisions regarding proposed sources and modifications that may affect visibility in a Federal Class I area reflect federal regulatory requirements at 40 CFR 51.307(a)(1) governing visibility protection in state NSR programs.[19] EPA notes that the proposed changes to North Carolina's FLM notification provisions are consistent with a letter EPA sent to North Carolina officials on April 16, 2013, which is included in the docket for this proposed rulemaking. In that letter, EPA generally concurred (with some exceptions) with North Carolina's expressed understanding of EPA's interpretation of the federal requirements governing the evaluation of the visibility impacts of new and modified sources on Class I areas under the PSD permitting program. Specifically, EPA affirmed that the process for determining whether a proposed new source or modification will cause an "adverse impact on visibility" in a Class I area is a two-step process. The first step requires an assessment of visibility impairment based on how visibility would change from what would have existed in the absence of any human-caused pollution.

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[17] Paragraph (v) establishes the numerical $PM_{2.5}$ increments. Paragraph (q) addresses the Class I $PM_{2.5}$ variances. Paragraph (e) incorporates paragraph (v) by reference. EPA is proposing to disapprove 15A NCAC 02D .0530, paragraphs (e), (q), and (v) in part, rather than in their entirety, because the paragraphs also include previously approved PM_{10} increment requirements. Specifically, in addition to making the $PM_{2.5}$-related changes to these paragraphs, North Carolina also revised 15A NCAC 02D .0530, paragraphs (e), (q), and (v), to directly incorporate the PM_{10} increments. Previously, North Carolina had incorporated the PM_{10} increments into 15A NCAC 02D .0530 by reference to the CFR. EPA is proposing to approve the PM_{10}-related changes to paragraphs (e), (q), and (v).

[18] Currently, there are no nonattainment areas in the State, and thus the list of nonattainment areas approved in the current SIP is out of date.

[19] FLM notification is needed to enable the FLMs to fulfill their obligation under 50 CFR 51.166(p)(2) "to protect the air quality related values (including visibility) of [Class I lands] and to consider, in consultation with the Administrator, whether a proposed source or modification would have an adverse impact on such values."

This analysis must be provided to the appropriate FLM(s) regardless of whether the Class I increment is exceeded. The second step in the analysis, the determination of whether the source will have an adverse impact on visibility, requires a more holistic evaluation of the various factors affecting visibility, potentially including current visibility conditions and whether the State is on track toward improving visibility. EPA concluded that because North Carolina's SIP-approved regulations at 15A NCAC 02D .0530(b) incorporate by reference the key federal regulatory provisions,[20] North Carolina's FLM notification provisions are consistent with federal visibility requirements. North Carolina's proposed SIP revision would incorporate an additional FLM notification mechanism into North Carolina's NSR procedures (generally requiring FLM notification of any PSD or NNSR permit application regardless of whether the proposed source or modification may affect visibility in a Class I area) and therefore does not conflict with the federal FLM notification requirements described above.[21] Accordingly, EPA is proposing to approve the changes to 15A NCAC 02D .0530(t) and 15A NCAC 02D .0531(m) provided in North Carolina's second May 16, 2011, SIP submittal.

Lastly, North Carolina's September 5, 2013, SIP submittal includes several administrative and typographical changes for the State's NSR regulations at 15A NCAC 02D .0530 (PSD) and 15A NCAC 02D .0531 (NNSR). EPA is proposing to approve these changes to the extent that they do not relate to 2010 PSD $PM_{2.5}$ Rule.[22] Specifically, EPA is proposing to approve all of the changes to 15A NCAC 02D .0531 (NNSR) and all of the changes to 15A NCAC 02D .0530 (PSD) except the portions of paragraphs 15A NCAC 02D .0530(e), (q), and (v) that pertain to $PM_{2.5}$ increments. As explained above, EPA is proposing to disapprove the portions of paragraphs 15A NCAC 02D .0530(e), (q), and (v) that pertain to $PM_{2.5}$ increments because they are not associated with the correct major source baseline date.

In sum, EPA is proposing to approve into the SIP the versions of 15A NCAC 02D .0530 (PSD) and 15A NCAC 02D .0531 (NNSR) that became effective in the state on September 1, 2013, except the portions of paragraphs 15A NCAC 02D .0530(e), (q), and (v) that pertain to $PM_{2.5}$ increments. EPA is proposing to disapprove North Carolina's September 5, 2013, submittal with respect to the $PM_{2.5}$-increment-related portions of paragraphs 15A NCAC 02D .0530(e), (q), and (v).

IV. What is EPA's analysis of the PSD elements for North Carolina's infrastructure SIP submittals?

As mentioned above, as a result of this proposed rule to partially disapprove the PSD increment portion of North Carolina's September 5, 2013, SIP submittal, EPA is proposing to partially approve and partially disapprove the PSD elements of the North Carolina's infrastructure SIP submittals for the 2008 lead NAAQS (received on July 20, 2012); the 2008 8-hour ozone NAAQS (received on November 2, 2012); the 2010 SO_2 NAAQS (received March 18, 2014); the 2010 NO_2 NAAQS (received on August 23, 2013); and the 2012 $PM_{2.5}$ NAAQS (received on December 4, 2015). Further, EPA is proposing to convert the conditional approval of the PSD elements for North Carolina's 1997 $PM_{2.5}$ infrastructure submittal (dated April 1, 2008), and North Carolina's 2006 $PM_{2.5}$ infrastructure submittal (dated September 21, 2009) to partial approvals and partial disapprovals. The background for infrastructure submittal requirements related to PSD is provided below, followed by a summary of EPA's analysis of the PSD elements for North Carolina's 1997 $PM_{2.5}$, 2006 $PM_{2.5}$, 2008 lead, 2008 8-hour ozone, 2010 NO_2, 2010 SO_2 and 2012 $PM_{2.5}$ NAAQS infrastructure SIP submittals. In a technical support document for this proposed rulemaking, EPA provides more information on infrastructure requirements and how EPA reviews state submittals related to these requirements.

By statute, SIPs meeting the requirements of sections 110(a)(1) and (2) of the CAA are to be submitted by states within three years after promulgation of a new or revised NAAQS to provide for the implementation, maintenance, and enforcement of the new or revised NAAQS. EPA has historically referred to these SIP submittals made for the purpose of satisfying the requirements of sections 110(a)(1) and 110(a)(2) as "infrastructure SIP" submittals. Sections 110(a)(1) and (2) require states to address basic SIP elements such as for monitoring, basic program requirements, and legal authority that are designed to assure attainment and maintenance of the newly established or revised NAAQS. More specifically, section 110(a)(1) provides the procedural and timing requirements for infrastructure SIPs. Section 110(a)(2) lists specific elements that states must meet for the infrastructure SIP requirements related to a newly established or revised NAAQS. The contents of an infrastructure SIP submittal may vary depending upon the data and analytical tools available to the state, as well as the provisions already contained in the state's implementation plan at the time in which the state develops and submits the submittal for a new or revised NAAQS.

A. PSD Elements for Infrastructure Submittals for the 2008 Lead, 2008 8-Hour Ozone, 2010 NO_2, 2010 SO_2 and 2012 $PM_{2.5}$ NAAQS

The PSD elements for infrastructure requirements are contained in section 110(a)(2)(C), 110(a)(2)(D)(i)(II) (also known as prong 3), and 110(a)(2)(J). For the remainder of this proposed rulemaking, EPA's intent in referring to "PSD elements" is to address the PSD requirements in sections 110(a)(2)(C), 110(a)(2)(D)(i)(II) (also known as prong 3), and 110(a)(2)(J). More detail regarding the aforementioned 110(a)(2) requirements related to PSD is provided below.

Section 110(a)(2)(C) has three components that must be addressed in infrastructure SIP submittals: Enforcement, state-wide regulation of new and modified minor sources and minor modifications of major sources; and PSD permitting of new major sources and major modifications in areas designated attainment or unclassifiable as required by CAA title I part C (*i.e.*, the major source PSD program). With regard to section 110(a)(2)(C), this proposed action only addresses North Carolina's infrastructure SIP submittals with respect to the major source PSD program.

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[20] When approving these provisions into North Carolina's SIP, EPA specifically noted that North Carolina's SIP incorporates the federal definitions of "adverse impact on visibility" and "visibility impairment." 51 FR 2695 (January 21, 1986). North Carolina's NNSR regulations also incorporate by reference the federal regulatory definitions pertaining to visibility impact assessment. *See* 15A NCAC 02D .0531(a).

[21] Under previously approved North Carolina SIP provisions, North Carolina must notify the FLMs of any proposed new source or modification that may affect visibility in a Class I area and provide the FLMs with an analysis of the potential visibility impact. General FLM notification of all permit applications pursuant to the SIP revision proposed for approval in today's notice would not replace North Carolina's more specific, existing SIP obligations regarding FLM notification of proposed new or modified sources that may affect visibility in a Class I area.

[22] For example, aside from the $PM_{2.5}$-related changes, North Carolina also revised 15A NCAC 02D .0530, paragraphs (e), (q), and (v), to directly incorporate the PM_{10} increments. Previously, North Carolina had incorporated the PM_{10} increments into 15A NCAC 02D .0530 by reference to the CFR. North Carolina's decision to instead incorporate the PM_{10} increments directly into state regulations does not change the PM_{10} increment requirements under North Carolina's PSD program and does not impact EPA's prior determination that North Carolina's SIP appropriately incorporates the federal PM_{10} increments. Therefore, EPA proposes to approve North Carolina's proposed PM_{10}-related changes to paragraphs (e), (q), and (v) of 15A NCAC 02D .0530.

Section 110(a)(2)(D)(i) has two components; 110(a)(2)(D)(i)(I) and 110(a)(2)(D)(i)(II). Each of these components has two subparts resulting in four distinct components, commonly referred to as "prongs," that must be addressed in infrastructure SIP submittals. The first two prongs, which are codified in section 110(a)(2)(D)(i)(I), are provisions that prohibit any source or other type of emissions activity in one state from contributing significantly to nonattainment of the NAAQS in another state ("prong 1"), and interfering with maintenance of the NAAQS in another state ("prong 2"). The third and fourth prongs, which are codified in section 110(a)(2)(D)(i)(II), are provisions that prohibit emissions activity in one state from interfering with measures required to prevent significant deterioration of air quality in another state ("prong 3"), or to protect visibility in another state ("prong 4"). With regard to section 110(a)(2)(D)(i), this proposed action only addresses North Carolina's infrastructure SIP submittals for prong 3.

Section 110(a)(2)(J) has four components that must be addressed in infrastructure SIP submittals: (1) consultation with government officials, (2) public notification, (3) PSD, and (4) visibility protection. With regard to section 110(a)(2)(J), today's proposed action only addresses North Carolina's infrastructure SIP submittals for PSD.

Regarding the PSD elements of sections 110(a)(2)(C) and (J), EPA interprets the CAA to require each state to make, for each new or revised NAAQS, an infrastructure SIP submittal that demonstrates that the state has a complete PSD permitting program meeting the current requirements for all regulated NSR pollutants. The requirements of the PSD element of section 110(a)(2)(D)(i)(II) (also known as prong 3) may also be satisfied by demonstrating that the air agency has a complete PSD permitting program correctly addressing all regulated NSR pollutants.

As described in EPA's September 13, 2013, guidance,[23] an infrastructure SIP submittal should demonstrate that one or more air agencies has the authority to implement a comprehensive PSD permit program under CAA title I part C, for all PSD-subject sources located in areas that are designated attainment or unclassifiable for one or more NAAQS. EPA interprets the PSD elements to require that a state's infrastructure SIP submission for a particular NAAQS demonstrate that the state has a complete PSD permitting program in place covering the structural PSD requirements for all regulated NSR pollutants. A state's PSD permitting program is complete for the PSD elements if EPA has already approved or is simultaneously approving the state's SIP with respect to all structural PSD requirements that are due under the EPA regulations or the CAA on or before the date of the EPA's proposed action on the infrastructure SIP submission. EPA is proposing to partially approve the PSD elements of North Carolina's infrastructure SIP submittals for the 2008 lead, 2008 8-hour ozone, 2010 NO$_2$, 2010 SO$_2$, and 2012 PM$_{2.5}$ NAAQS and to disapprove these submittals with respect to the PM$_{2.5}$ increment requirements of 2010 PSD PM$_{2.5}$ Rule.

1. 2008 Lead NAAQS

On October 15, 2008, EPA revised the primary and secondary NAAQS for lead to 0.15 $\mu g/m^3$. 73 FR 66964 (November 12, 2008). States were required to submit infrastructure SIP submittals for the 2008 8-hour lead NAAQS to EPA no later than October 15, 2011. For the 2008 lead NAAQS, this proposed action only addresses the PSD elements of North Carolina's infrastructure SIP submittals received on July 20, 2012. As explained above, EPA is proposing to disapprove North Carolina's September 5, 2013, SIP revision related to the PM$_{2.5}$ increment requirements. Consequently, North Carolina's SIP does not contain a fully approvable PSD program covering the structural PSD requirements for all NAAQS. EPA is thus proposing to approve in part the PSD elements for North Carolina's July 20, 2012, infrastructure submittal for the 2008 lead NAAQS, and disapprove this submittal with respect to the PM$_{2.5}$ increment requirements of 2010 PSD PM$_{2.5}$ Rule. EPA took action on other portions of North Carolina's July 20, 2012, SIP submittal in separate rulemakings. *See* 80 FR 12343 (March 9, 2015); 80 FR 67645 (November 3, 2015).

2. 2008 8-Hour Ozone NAAQS

On March 12, 2008, EPA revised the 8-hour ozone NAAQS to 0.075 parts per million. 73 FR 16436 (March 27, 2008). States were required to submit infrastructure SIP submittals for the 2008 8-hour ozone NAAQS to EPA no later than March 12, 2011. For the 2008 8-hour ozone NAAQS, this proposed action only addresses the PSD elements of North Carolina's infrastructure SIP submittal received on November 2, 2012. As explained above, EPA is proposing to disapprove North Carolina's September 5, 2013, SIP revision related to the PM$_{2.5}$ increment requirements. Consequently, North Carolina's SIP does not contain a fully approvable PSD program covering the structural PSD requirements for all NAAQS. EPA is thus proposing to approve in part the PSD elements for North Carolina's November 2, 2012, infrastructure submittal for the 2008 8-hour ozone NAAQS, and disapprove this submittal with respect to the PM$_{2.5}$ increment requirements of 2010 PSD PM$_{2.5}$ Rule. EPA took action on portions of North Carolina's November 2, 2012, SIP submittal in separate rulemakings. *See* 80 FR 67645 (November 3, 2015); 80 FR 68453 (November 5, 2015).

3. 2010 NO$_2$ NAAQS

On January 22, 2010, EPA established a new 1-hour primary NAAQS for NO$_2$ at a level of 100 parts per billion (ppb), based on a 3-year average of the 98th percentile of the yearly distribution of 1-hour daily maximum concentrations. *See* 75 FR 6474 (February 9, 2010). States were required to submit infrastructure SIP submittals for the 2010 1-hour NO$_2$ NAAQS to EPA no later than January 22, 2013. For the 2010 1-hour NO$_2$ NAAQS, this proposed action only addresses the PSD elements of North Carolina's infrastructure SIP submittal received on August 23, 2013. As explained above, EPA is proposing to disapprove North Carolina's September 5, 2013, SIP revision related to the PM$_{2.5}$ increment requirements. Consequently, North Carolina's SIP does not contain a fully approvable PSD program covering the structural PSD requirements for all NAAQS. EPA is thus proposing to approve in part the PSD elements for North Carolina's August 23, 2013, infrastructure submittal for the 2010 1-hour NO$_2$ NAAQS, and disapprove this submittal with respect to the PM$_{2.5}$ increment requirements of 2010 PSD PM$_{2.5}$ Rule. EPA will take action on the remainder of North Carolina's August 23, 2013 SIP submittal through a separate rulemaking.

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[23] EPA's September 13, 2013, guidance, titled "Guidance on Infrastructure State Implementation Plan (SIP) Elements under Clean Air Act Sections 110(a)(1) and 110(a)," provides advice on the development of infrastructure SIPs for the 2008 ozone NAAQS, the 2010 nitrogen dioxide NAAQS, the 2010 sulfur dioxide NAAQS, and the 2012 PM$_{2.5}$ NAAQS, as well as infrastructure SIPs for new or revised NAAQS promulgated in the future.

4. 2010 SO_2 NAAQS

On June 2, 2010, EPA revised the primary SO_2 NAAQS to an hourly standard of 75 ppb based on a 3-year average of the annual 99th percentile of 1-hour daily maximum concentrations. *See* 75 FR 35520 (June 22, 2010). States were required to submit infrastructure SIP submittals for the 2010 1-hour SO_2 NAAQS to EPA no later than June 2, 2013. For the 2010 1-hour SO_2 NAAQS, this proposed action only addresses the PSD elements of North Carolina's infrastructure SIP submittal received on March 18, 2014. As explained above, EPA is proposing to disapprove North Carolina's September 5, 2013, SIP revision related to the $PM_{2.5}$ increment requirements. Consequently, North Carolina's SIP does not contain a fully approvable PSD program covering the structural PSD requirements for all NAAQS. EPA is thus proposing to approve in part the PSD elements for North Carolina's March 18, 2014, infrastructure submittal for the 2010 1-hour SO_2 NAAQS, and disapprove this submittal with respect to the $PM_{2.5}$ increment requirements of 2010 PSD $PM_{2.5}$ Rule. EPA will take action on the remainder of North Carolina's March 18, 2014, SIP submittal through a separate rulemaking.

5. 2012 $PM_{2.5}$ NAAQS

On December 14, 2012, EPA revised the primary annual $PM_{2.5}$ NAAQS to 12 μg/m³. *See* 78 FR 3086 (January 15, 2013). An area will meet the standard if the three-year average of its annual average $PM_{2.5}$ concentration (at each monitoring site in the area) is less than or equal to 12.0 μg/m³. States were required to submit infrastructure SIP submittals for the 2012 $PM_{2.5}$ NAAQS to EPA no later than December 14, 2015. For the 2012 $PM_{2.5}$ NAAQS, this proposed action only addresses the PSD elements of North Carolina's infrastructure SIP submittal received on December 4, 2015. As explained above, EPA is proposing to disapprove North Carolina's September 5, 2013, SIP revision related to the $PM_{2.5}$ increment requirements. Consequently, North Carolina's SIP does not contain a fully approvable PSD program covering the structural PSD requirements for all NAAQS. EPA is thus proposing to approve in part the PSD elements for North Carolina's December 4, 2015, infrastructure submittal for the 2012 $PM_{2.5}$ NAAQS, and disapprove this submittal with respect to the $PM_{2.5}$ increment requirements of 2010 PSD $PM_{2.5}$ Rule. EPA will take action on the remainder of North Carolina's December 4, 2015, SIP submittal through a separate rulemaking.

B. PSD Elements for Infrastructure Submittals for the 1997 and 2006 $PM_{2.5}$ NAAQS

On October 16, 2012, and March 26, 2013, EPA conditionally approved the PSD elements of section 110(a)(2)(C) and (J) of North Carolina's SIP submittals for the 1997 $PM_{2.5}$ and 2006 $PM_{2.5}$ NAAQS, dated April 1, 2008, and September 21, 2009, respectively. *See* 77 FR 63234 and 78 FR 18241. On April 1, 2008, and September 21, 2009, North Carolina submitted infrastructure SIP submittals for the 1997 $PM_{2.5}$ and 2006 $PM_{2.5}$ NAAQS, respectively. The conditional approvals were granted on the condition that North Carolina would submit complete SIP revisions to address deficiencies in relation to the State's NSR regulations within one year of publication of the final conditional approvals.[24]

EPA noted in the October 16, 2012, final rulemaking that "[i]f North Carolina fails to submit these revisions by October 16, 2013, this conditional approval will automatically become a disapproval on that date and EPA will issue a finding of disapproval. EPA is not required to propose the finding of disapproval. If the conditional approval is converted to a disapproval, the final disapproval triggers the Federal Implementation Plan requirement under section 110(c). However, if the State meets its commitment within the applicable timeframe, the conditionally approved submittal will remain a part of the SIP until EPA takes final action approving or disapproving the new submittal. If EPA disapproves the new submittal, the conditionally approved submittal will also be disapproved at that time." EPA reiterated this condition in the March 26, 2013, final rulemaking.

North Carolina provided its submittal purporting to correct the deficiencies with the State's NSR program on September 5, 2013. As mentioned in EPA's October 16, 2012, and March 26, 2013, final rulemakings, since North Carolina met the deadline to provide the corrective SIP revision, the conditional approval remains in effect until EPA concludes its action on the corrective SIP revision. This proposed action is to disapprove North Carolina's September 5, 2013, SIP submittal (*i.e.*, the corrective SIP) in relation to the baseline for the $PM_{2.5}$ PSD increment—a critical component for the State's NSR program. Thus, EPA is proposing to convert EPA's previous conditional approval of these PSD elements of North Carolina's 1997 $PM_{2.5}$ and 2006 $PM_{2.5}$ NAAQS infrastructure SIP submittals to a partial approval and a partial disapproval for the $PM_{2.5}$ increment component.

V. Incorporation by Reference

In this rulemaking, EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is proposing to incorporate by reference the portions of North Carolina's regulations 15A NCAC 02D .0530 and 15A NCAC 02D .0531, entitled "Prevention of Significant Deterioration" and "Sources in Nonattainment Areas," respectively, that EPA is proposing to approve herein. EPA is not proposing to incorporate provisions for which the Agency is proposing to disapprove. EPA has made, and will continue to make, these documents generally available electronically through *www.regulations.gov* and/or in hard copy at the EPA Region 4 office (see the **ADDRESSES** section of this preamble for more information).

VI. Proposed Actions

EPA is proposing to approve, in part, and disapprove, in part, changes to the North Carolina SIP, provided by the NC DEQ, to EPA on May 16, 2011, (two submittals) and September 5, 2013. These changes modify North Carolina's NSR—PSD and NNSR—permitting regulations codified at 15A 02D .0530—*Prevention of Significant Deterioration* and 15A NCAC 02D.0531—*Sources in Nonattainment Areas,* and include the adoption of some federal requirements respecting implementation of the $PM_{2.5}$ NAAQS through the NSR permitting program. Specifically, EPA is proposing to approve the State's changes as they relate to the requirements to comply with EPA's 2008 $PM_{2.5}$ NSR Rule and the State's miscellaneous changes as described in Section II.C of this proposed rulemaking. EPA is proposing to disapprove North Carolina's September 5, 2013, SIP submittal as it relates to the requirements to comply with EPA's 2010 PSD $PM_{2.5}$ Rule. If EPA finalizes all of the actions proposed in today's notice, the versions of 15A NCAC 02D .0530 (PSD) and 15A NCAC 02D .0531 (NNSR) that became effective in the state on September 1, 2013, will be incorporated into North Carolina's SIP, with the exception of the portions of paragraphs 15A NCAC 02D .0530(e), (q), and (v) that pertain to $PM_{2.5}$ increments. EPA's proposed disapproval of North Carolina's September 5, 2013, SIP submittal as it relates to the requirements to comply with EPA's 2010 PSD $PM_{2.5}$ Rule, if finalized, will trigger the requirement under section 110(c) for EPA to promulgate a FIP no later than two years from the date of the disapproval unless the State corrects the deficiency through a SIP revision and EPA approves the SIP revision before EPA promulgates such a FIP.

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[24] In North Carolina's July 10, 2012, request for conditional approval of the State's infrastructure submittal for the 2006 $PM_{2.5}$ NAAQS, the State committed to revising its rules to reflect the 40 tons per year significance level for NO_X as a $PM_{2.5}$ precursor and to adopt the 2006 $PM_{2.5}$ PSD increments.

As a result of the proposed disapproval of a portion of the State's NSR requirements, EPA is proposing to disapprove the PSD elements of the North Carolina's infrastructure SIP submittals for the 2008 lead, 2008 8-hour ozone, 2010 SO_2, 2010 NO_2 and the 2012 $PM_{2.5}$ NAAQS; and is proposing to convert the Agency's previous conditional approvals of the PSD elements of North Carolina's infrastructure SIP submittals for the 1997 Annual $PM_{2.5}$ and 2006 24-hour $PM_{2.5}$ NAAQS to disapprovals. North Carolina did not submit these infrastructure SIPs to meet requirements for Part D of the CAA or a SIP call; therefore, if EPA takes final action to disapprove the PSD portions of these submittals, no sanctions will be triggered. However, if EPA finalizes this proposed disapproval action, that final action will trigger the requirement under section 110(c) for EPA to promulgate a FIP no later than two years from the date of the disapproval unless the State corrects the deficiency through a SIP revision and EPA approves the SIP revision before EPA promulgates such a FIP.

VII. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submittal that complies with the provisions of the Act and applicable federal regulations. *See* 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submittals, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. This action approves, in part, and disapproves, in part, state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. EPA is proposing to determine that the PSD portion of some of the aforementioned SIP submittals do not meet federal requirements. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: April 29, 2016.

Heather McTeer Toney,

Regional Administrator, Region 4.

[FR Doc. 2016–10894 Filed 5–9–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2016–0107; FRL–9946–18–Region 8]

Approval and Promulgation of Air Quality Implementation Plans; Interstate Transport for Utah

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing action on the portions of two submissions from the State of Utah that are intended to demonstrate that the State Implementation Plan (SIP) meets certain interstate transport requirements of the Clean Air Act (Act or CAA). These submissions address the 2008 ozone National Ambient Air Quality Standards (NAAQS) and 2008 lead (Pb) NAAQS. Specifically, the EPA is proposing to approve interstate transport prongs 1 and 2 for the 2008 Pb NAAQS, and proposing to disapprove prongs 1 and 2 for the 2008 ozone NAAQS.

DATES: Comments must be received on or before June 9, 2016.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R08–OAR–2016–0107 at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from regulations.gov. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Adam Clark, Air Program, U.S. Environmental Protection Agency (EPA), Region 8, Mail Code 8P–AR, 1595 Wynkoop Street, Denver, Colorado 80202–1129. (303) 312–7104, *clark.adam@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

What should I consider as I prepare my comments for EPA?

1. *Submitting Confidential Business Information (CBI).* Do not submit CBI to EPA through *http://www.regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information on a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

- Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** volume, date, and page number);
- Follow directions and organize your comments;
- Explain why you agree or disagree;
- Suggest alternatives and substitute language for your requested changes;
- Describe any assumptions and provide any technical information and/or data that you used;
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced;
- Provide specific examples to illustrate your concerns, and suggest alternatives;
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats; and
- Make sure to submit your comments by the comment period deadline identified.

II. Background

On March 12, 2008, EPA revised the levels of the primary and secondary 8-hour ozone standards to 0.075 parts per million (ppm) (73 FR 16436, March 27, 2008). On October 15, 2008, EPA revised the level of the primary and secondary Pb NAAQS to 0.15 $\mu g/m^3$ (73 FR 66964, Nov. 12, 2008).

Pursuant to section 110(a)(1) of the CAA, states are required to submit SIPs meeting the applicable requirements of section 110(a)(2) within three years after promulgation of a new or revised NAAQS or within such shorter period as EPA may prescribe. Section 110(a)(2) requires states to address structural SIP elements such as requirements for monitoring, basic program requirements, and legal authority that are designed to provide for implementation, maintenance, and enforcement of the NAAQS. The SIP submission required by these provisions is referred to as the "infrastructure" SIP. Section 110(a) imposes the obligation upon states to make a SIP submission to the EPA for a new or revised NAAQS, but the contents of individual state submissions may vary depending upon the facts and circumstances.

CAA Section 110(a)(2)(D)(i)(I) requires SIPs to include provisions prohibiting any source or other type of emissions activity in one state from emitting any air pollutant in amounts that will contribute significantly to nonattainment, or interfere with maintenance, of the NAAQS in another state (known as the "good neighbor" provision). The two provisions of this section are referred to as prong 1 (significant contribution to nonattainment) and prong 2 (interfere with maintenance). Section 110(a)(2)(D)(i)(II) requires SIPs to contain adequate provisions to prohibit emissions that will interfere with measures required to be included in the applicable implementation plan for any other state under part C to prevent significant deterioration of air quality (prong 3) or to protect visibility (prong 4).

In this action, the EPA is only addressing prongs 1 and 2 of CAA section 110(a)(2)(D)(i) with regard to the 2008 ozone and 2008 Pb NAAQS.

III. State Submissions and EPA's Assessment

The Utah Department of Environmental Quality (Department or UDEQ) submitted a certification of Utah's infrastructure SIP for the 2008 Pb NAAQS on January 19, 2012, a certification of Utah's infrastructure SIP for the 2008 ozone NAAQS on January 31, 2013, and a supplement regarding CAA section 110(a)(2)(D)(i)(I) with respect to the 2008 ozone NAAQS on December 22, 2015.[1]

Each of these infrastructure certifications addressed all of the infrastructure elements including element (D).[2] In this action, we are only addressing element (D) prongs 1 and 2 from the 2008 Pb certification, 2008 ozone certification, and the December 22, 2015 supplement which addressed prongs 1 and 2 for the 2008 ozone NAAQS. All other infrastructure elements from these certifications are being addressed in separate actions.

2008 Ozone NAAQS

In its January 31, 2013 2008 ozone infrastructure submittal, UDEQ addressed 110(a)(2)(D)(i)(I) prongs 1 and 2 by citing EPA Administrator Gina McCarthy's November 19, 2012 memo[3] which outlined the EPA's intention to abide by the decision of the United States Court of Appeals for the District of Columbia Circuit (D.C. Circuit) in *EME Homer City Generation, L.P.* v. *E.P.A.*, 696 F.3d 7 (D.C. Cir. 2012)). The *EME Homer City* decision addressed the Cross-State Air Pollution Rule (CSAPR) promulgated by the EPA to address the interstate transport requirements under section 110(a)(2)(D)(i)(I) with respect to the 1997 ozone NAAQS, the 1997 fine particulate matter ($PM_{2.5}$) NAAQS, and the 2006 $PM_{2.5}$ NAAQS. Among other things, the D.C. Circuit held that states did not have an obligation to submit SIPs addressing section 110(a)(2)(D)(i)(I) interstate transport requirements as to any NAAQS until the EPA first quantified each state's emissions reduction obligation. *Id.* at 30–31. In its submittal, the Department noted that the EPA had not quantified Utah's transport obligation as to the 2008 ozone NAAQS and that Utah's infrastructure SIP was therefore adequate with regard to prongs 1 and 2 of CAA section 110(a)(2)(D)(i)(I).

Subsequent to the UDEQ submission, on April 29, 2014, the U.S. Supreme Court reversed and remanded the D.C. Circuit's *EME Homer City* decision on CSAPR and held, among other things, that under the plain language of the CAA, states must submit SIPs addressing interstate transport requirements of CAA section 110(a)(2)(D)(i)(I) within three years of the promulgation of a new or revised NAAQS, regardless of whether EPA first provides guidance, technical data or rulemaking to quantify the state's obligation. *EPA* v. *EME Homer City Generation, L.P.*, 134 S. Ct. 1584, 1601

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[1] The 110(a)(2)(D)(i)(I) 2008 ozone supplement was submitted as part of Utah's infrastructure SIP certification for the 2012 $PM_{2.5}$ NAAQS.

[2] For discussion of other infrastructure elements, see EPA's "Guidance on Infrastructure State Implementation Plan (SIP) Elements under Clean Air Act Sections 110(a)(1) and (2)," September 13, 2013.

[3] Memo from Gina McCarthy to Air Division Directors, Regions 1–10 re: Next Steps for Pending Redesignation Requests and State Implementation Plan Actions Affected by the Recent Court Decision Vacating the 2011 Cross-State Air Pollution Rule (Nov. 19, 2012).

(2014). UDEQ therefore additionally addressed 110(a)(2)(D)(i) prongs 1 and 2 for the 2008 ozone NAAQS as part of its December 22, 2015 infrastructure submittal that otherwise addressed the 2012 $PM_{2.5}$ NAAQS. As stated, the EPA is proposing action on both the January 31, 2013 and December 22, 2015 certifications with regard to prongs 1 and 2 for the 2008 ozone NAAQS.

In its subsequent December 22, 2015 infrastructure submittal, UDEQ acknowledged the changed legal landscape, and asserted that emissions from the State did not significantly contribute to nonattainment or interfere with maintenance of the 2008 ozone NAAQS in any other state. The Department cited air quality modeling assessing interstate transport of ozone that was released by the EPA on August 4, 2015, and explained that it did not consider the modeled contribution levels to nonattainment and maintenance receptors in the Denver, Colorado area and in southern California to be significant.

As noted by UDEQ, the EPA shared technical information with states to assist them with meeting section 110(a)(2)(D)(i)(I) requirements for the 2008 ozone NAAQS. The EPA developed this technical information following the same approach used to evaluate interstate contribution in CSAPR in order to support the recently proposed Cross-State Air Pollution Rule Update for the 2008 Ozone NAAQS, 80 FR 75706 (Dec. 3, 2015) ("CSAPR Update Rule"). In CSAPR, the EPA used detailed air quality analyses to determine whether an eastern state's contribution to downwind air quality problems was at or above specific thresholds. If a state's contribution did not exceed the specified air quality threshold, the state was not considered "linked" to identified downwind nonattainment and maintenance receptors and was therefore not considered to significantly contribute or interfere with maintenance of the standard in those downwind areas. If a state exceeded that threshold, the state's emissions were further evaluated, taking into account both air quality and cost considerations, to determine what, if any, emissions reductions might be necessary. For the reasons stated below, we believe it is appropriate to use the same approach the EPA used in CSAPR to establish an air quality threshold for the evaluation of interstate transport requirements for the 2008 ozone standard.

On August 4, 2015, the EPA issued a Notice of Data Availability (NODA) containing air quality modeling data that projects interstate transport contributions for the year 2017 for the 2008 8-hour ozone NAAQS.[4] The modeling data released in the NODA was also used to support the proposed CSAPR Update Rule and is also cited by UDEQ in its updated 2008 ozone submittal. Since the moderate area attainment date for the 2008 ozone standard is July 11, 2018, states will use 2015 through 2017 ambient ozone data in order to demonstrate attainment by this attainment deadline—meaning the 2017 ozone season will be the last full season from which data can be used to determine attainment of the NAAQS. The D.C. Circuit's decision in *North Carolina* v. *EPA* requires that the EPA coordinate interstate transport compliance deadlines with downwind nonattainment deadlines. As noted in EPA's proposed CSAPR Update Rule, the Agency interprets the *North Carolina* decision to compel EPA to identify upwind reductions and implementation programs to achieve these reductions, to the extent possible, for the 2017 ozone season. Therefore, the EPA determined that 2017 is an appropriate future year to model for the purpose of examining interstate transport for the 2008 8-hour ozone NAAQS. The Agency used photochemical air quality modeling to project ozone concentrations at air quality monitoring sites to 2017 and estimated state-by-state ozone contributions to those 2017 concentrations. This modeling used the Comprehensive Air Quality Model with Extensions (CAMx version 6.11) to model the 2011 base year, and the 2017 future base case emissions scenarios to identify projected nonattainment and maintenance sites with respect to the 2008 8-hour ozone NAAQS in 2017. The EPA used nationwide state-level ozone source apportionment modeling (CAMx Ozone Source Apportionment Technology/Anthropogenic Precursor Culpability Analysis technique) to quantify the contribution of 2017 base case nitrogen oxides (NO_X) and volatile organic compounds (VOC) emissions from all sources in each state to the 2017 projected receptors. The air quality model runs were performed for a modeling domain that covers the 48 contiguous United States and adjacent portions of Canada and Mexico.

The EPA used the modeling released in the NODA to support its proposed CSAPR Update rulemaking (80 FR 75706, Dec. 3, 2015). As discussed in our CSAPR Update Rule proposal for the 2008 ozone NAAQS, the air quality modeling (1) identified locations in the U.S. where the EPA anticipates nonattainment or maintenance issues in 2017 for the 2008 ozone NAAQS (these are identified as nonattainment and maintenance receptors), and (2) quantified the projected contributions from emissions from upwind states to downwind ozone concentrations at the receptors in 2017. *Id.* at 75720–30. Consistent with the framework established in CSAPR, the EPA proposed to use a threshold of one percent of the 2008 ozone NAAQS of 75 ppb (0.75 ppb) to identify linkages between upwind states and the downwind nonattainment and maintenance receptors. In the proposed CSAPR Update Rule, the EPA considered eastern states[5] whose contributions to a specific receptor meet or exceed the threshold "linked" to that receptor and we analyzed these states further to determine if emissions reductions might be required from each state to address the downwind air quality problem. *Id.* at 75728.

As to western states, the EPA noted that the 2017 implementation timeframe constrained the opportunity to evaluate the applicability of these criteria to such states and whether additional criteria should be considered in certain circumstances as to western states. Therefore, the EPA proposed to focus the rulemaking on the eastern states while requesting comment on whether to include western states. *Id.* at 75709. Consistent with our statements in the proposed CSAPR Update Rule, the EPA intends to address western states, like Utah, on a case-by-case basis. The modeling data released in the NODA on August 4, 2015, are the most up-to-date information the EPA has developed to inform our analysis of upwind state linkages to downwind air quality problems. We intend to use these data to help evaluate the state's submittals and any potential emission reduction obligations as to the 2008 ozone standard under section 110(a)(2)(D)(i)(I).

As noted earlier, in CSAPR the EPA proposed an air quality threshold of one percent of the applicable NAAQS and requested comment on whether one percent was appropriate.[6] The EPA evaluated the comments received and ultimately determined that one percent was an appropriately low threshold because there were important, even if relatively small, contributions to identified nonattainment and maintenance receptors from multiple upwind states. In response to commenters who advocated a higher or lower threshold than one percent, the EPA compiled the contribution modeling results for CSAPR to analyze the impact of different possible thresholds for the eastern United States. The EPA's analysis showed that the one percent threshold captures a high percentage of the total pollution transport affecting downwind states, while the use of higher thresholds would exclude increasingly larger percentages of total transport. For example, at a five percent threshold, the majority of interstate pollution transport affecting downwind receptors would be excluded.[7] In addition, the EPA determined that it was important to use a relatively lower one percent threshold because there are adverse health impacts associated with ambient ozone even at low levels.[8] The EPA also determined that a lower threshold such as 0.5 percent would result in relatively modest increases in the overall percentages of fine particulate matter and ozone pollution transport captured relative to the amounts captured at the one percent level. The EPA determined that a "0.5 percent threshold could lead to emission reduction responsibilities in additional states that individually have a very small impact on those receptors — an indicator that emission controls in those states are likely to have a smaller air quality impact at the downwind receptor. We are not convinced that selecting a threshold below one percent is necessary or desirable."[9]

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[4] Notice of Availability of the Environmental Protection Agency's Updated Ozone Transport Modeling Data for the 2008 Ozone National Ambient Air Quality Standard (NAAQS), 80 FR 46271 (August 4, 2015).

[5] For purposes of the proposed CSAPR Update Rule, "eastern" states refer to all contiguous states east of the Rocky Mountains, specifically not including: Montana, Wyoming, Colorado and New Mexico.

[6] CSAPR proposal, 75 FR 45210, 45237 (August 2, 2010).

In the final CSAPR, the EPA determined that one percent was a reasonable choice considering the combined downwind impact of multiple upwind states in the eastern United States, the health effects of low levels of fine particulate matter and ozone pollution, and the EPA's previous use of a one percent threshold in CAIR. The EPA used a single "bright line" air quality threshold equal to one percent of the 1997 8-hour ozone standard, or 0.08 ppm.[10] The projected contribution from each state was averaged over multiple days with projected high modeled ozone, and then compared to the one percent threshold. We concluded that this approach for setting and applying the air quality threshold for ozone was appropriate because it provided a robust metric, was consistent with the approach for fine particulate matter used in CSAPR, and because it took into account, and would be applicable to, any future ozone standards below 0.08 ppm.[11] The EPA has subsequently proposed to use the same threshold for purposes of evaluating interstate transport with respect to the 2008 ozone standard in eastern states in the CSAPR Update Rule.

The EPA's recent air quality modeling shows that multiple upwind states collectively contributed to projected downwind nonattainment or maintenance receptors in Colorado. In particular, the EPA found that the total upwind states' contribution to ozone concentrations (from linked and unlinked states) to identified downwind air quality problems in Colorado is about 11 percent.[12] Thus, the EPA has found that the collective contribution of emissions from upwind states represent a large portion of the ozone concentrations at projected nonattainment and maintenance receptors in Colorado. As noted, the Agency has consistently found that the one percent threshold is appropriate for identifying interstate transport linkages for states collectively contributing to downwind ozone nonattainment or maintenance problems because that threshold captures a high percentage of the total pollution transport affecting downwind receptors. The EPA believes contribution from an individual state equal to or above one percent of the NAAQS could be considered significant where the collective contribution of emissions from one or more upwind states is responsible for a considerable portion of the downwind air quality problem regardless of where the receptor is geographically located. In this case, five of the states contributing to those identified receptors, including Utah, contribute emissions greater than or equal to one percent of the 2008 ozone NAAQS. Given this data, the EPA is proposing to find that the NODA modeling and its use of the one percent threshold are also appropriate to determine linkages from Utah to downwind nonattainment and maintenance receptors in Colorado with respect to the 2008 ozone NAAQS.

Tables 1 and 2 summarize the air quality modeling results from the August 4, 2015 NODA modeling. The modeling indicates that Utah contributes emissions above the one percent threshold of 0.75 ppb with respect to four receptors in the Denver, Colorado area. These tables show the monitors in the Denver area to which Utah emissions are modeled to contribute above one percent of the 2008 ozone NAAQS.[13]

TABLE 1—MAINTENANCE RECEPTORS WITH UTAH CONTRIBUTION MODELED ABOVE 1%

Monitor I.D.	State	County	Utah modeled contribution (ppb)
80050002	Colorado	Arapahoe	1.66
80590011	Colorado	Jefferson	1.34

TABLE 2—NONATTAINMENT RECEPTORS WITH UTAH CONTRIBUTION MODELED ABOVE 1%

Monitor I.D.	State	County	Utah modeled contribution (ppb)
80350004	Colorado	Douglas	1.59

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[7] *See also* Air Quality Modeling Final Rule Technical Support Document, Appendix F, Analysis of Contribution Thresholds, Docket ID # EPA–hq–oar–2009–0491.

[8] CSAPR, 76 FR 48208, 48236–37 (August 8, 2011).

[9] *Id.*

[10] *Id.*

[11] *Id.*

[12] The stated 11% is based on the highest upwind contributions to nonattainment or maintenance receptors in each area. All nonattainment and maintenance receptors had upwind contributions at 9% or more.

[13] The NODA modeling had taken into account the shutdown of the Carbon Power Plant, which was shut down in April 2015. See Carbon Permit Revocation Letter, in the docket for this action.

TABLE 2—NONATTAINMENT RECEPTORS WITH UTAH CONTRIBUTION MODELED ABOVE 1%—Continued

Monitor I.D.	State	County	Utah modeled contribution (ppb)
80590006	Colorado	Jefferson	0.87

Utah's largest contribution to any projected downwind nonattainment site is 1.59 ppb, and its largest contribution to any projected downwind maintenance-only site is 1.66 ppb. Since the NODA modeling indicates that the contributions from Utah are above the one percent threshold of 0.75 ppb with respect to nonattainment and maintenance receptors in the Denver, Colorado area, the EPA is proposing to determine that Utah significantly contributes to nonattainment and interferences with maintenance of the 2008 ozone NAAQS for the Denver, Colorado area.

UDEQ states that, despite the modeling results, emissions from the State do not significantly contribute to nonattainment in the Denver area, but the State does not provide any technical analysis to explain why it believes the modeling results are inaccurate or why, if the results are accurate, the State's level of contribution to Denver-area receptors should be deemed insignificant. Moreover, UDEQ does not address the State's modeled contributions to projected downwind maintenance receptors identified by the EPA. Rather, UDEQ cites various SIP-approved area source rules which it asserts will result in additional reductions in ozone precursor emissions as further evidence that emissions from the State do not contribute significantly to nonattainment of the 2008 ozone NAAQS in any other state. The Department listed several VOC emissions limitations on various industries submitted as part of the State's greater $PM_{2.5}$ control strategy which were recently approved by EPA.[14] UDEQ also pointed to a rule prohibiting the sale of water heaters that do not comply with low NO_X emission rates which will go into effect on November 1, 2017. UDEQ argued that because NO_X and VOC are precursors to ozone, these emission limitations would further reduce ozone transport to nonattainment and maintenance receptors in both Colorado and California, but failed to quantify or explain how these limitations would significantly reduce Utah ozone emissions. UDEQ did not discuss emissions limits or reductions from any other source categories, such as large electric generating units (EGUs) within the State.

Though the EPA considers the measures UDEQ described to be beneficial in reducing ozone transport, UDEQ has not provided any analysis to demonstrate that the reductions will be sufficient to significantly reduce Utah ozone emissions. The Department did not quantify the total anticipated reductions in NO_X and VOC emissions from its listed regulations or evaluate the impact of those reductions in downwind air quality at the Denver area receptors. As explained above, the NODA modeling indicates that in spite of the measures Utah describes, emissions from sources in Utah contribute well above the one percent threshold of 0.75 ppb with respect to nonattainment and maintenance receptors in the Denver, Colorado area. UDEQ has not provided any technical analysis to contradict that information.

UDEQ also states in the 2015 submission that the State does not believe it significantly contributes or interferes with maintenance of the 2008 ozone NAAQS in southern California, citing the State's VOC and NO_X emission limitations. UDEQ also cites the general west to east wind direction in the western U.S. as further evidence that Utah emissions are unlikely to significantly impact ozone pollution in southern California. Although the State did not provide a particular technical analysis to support this conclusion, EPA's modeling released in the August 4, 2015 NODA confirms UDEQ's assertion that the State does not significantly contribute to nonattainment or interfere with maintenance in California.

As explained earlier, UDEQ's SIP submissions do not provide an adequate technical analysis demonstrating that the SIP contains adequate provisions prohibiting emissions that will significantly contribute to nonattainment or interfere with the 2008 ozone NAAQS in any other state. Moreover, EPA's most recent modeling indicates that emissions from Utah are projected to contribute to downwind nonattainment and maintenance receptors in the Denver, Colorado area. Accordingly, EPA proposes to disapprove the portion of the January 31, 2013 SIP submittal and the December 22, 2015 submittal addressing CAA section 110(a)(2)(D)(i)(I) prongs 1 and 2 with respect to the 2008 ozone NAAQS. EPA is soliciting public comments on this proposed action and will consider public comments received during the comment period.

2008 Pb NAAQS

UDEQ's analysis of potential interstate transport for the 2008 Pb NAAQS discussed the lack of sources with significant Pb emissions near the State's borders. The Department also noted that there are no Pb nonattainment areas in states neighboring Utah.

As noted in our October 14, 2011 Infrastructure Guidance Memo, there is a sharp decrease in Pb concentrations, at least in the coarse fraction, as the distance from a Pb source increases. *See* "Guidance on Infrastructure SIP Elements Required Under Sections 110(a)(1) and (2) for the 2008 Lead (Pb) National Ambient Air Quality Standards (NAAQS)." October 14, 2011 at 8. For this reason, the EPA found that the requirements of subsection 110(a)(2)(D)(i)(I) (prongs 1 and 2) could be satisfied through a state's assessment as to whether or not emissions from Pb sources located in close proximity to their state borders have emissions that impact the neighboring state such that they contribute significantly to nonattainment or interfere with maintenance in that state. *Id.* at 8. In that guidance document, the EPA further specified that any source appeared unlikely to contribute significantly to nonattainment unless it was located less than two miles from a state border and emitted at least 0.5 tons per year of Pb. UDEQ's 110(a)(2)(D)(i)(I) analysis specifically noted that there are no sources in the State that meet both of these criteria. EPA concurs with the State's analysis and conclusion that no Utah sources have the combination of Pb emission levels and proximity to nearby nonattainment or maintenance areas to contribute significantly to nonattainment in or interfere with maintenance by other states for this NAAQS. Utah's SIP is therefore adequate to ensure that such impacts do not occur. We are proposing to approve UDEQ's submittal with regard to the requirements of section 110(a)(2)(D)(i) prongs 1 and 2 for the 2008 Pb NAAQS.

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[14] For more detail, see EPA's final action on these area source rules at 81 FR 9343, February 25, 2016, and the associated docket at EPA–R08–OAR–2014–0369.

IV. Proposed Action

The EPA is proposing to approve CAA section 110(a)(2)(D)(i)(I) prongs 1 and 2 for the 2008 Pb NAAQS, and proposing to disapprove prongs 1 and 2 for the 2008 ozone NAAQS based on consideration of modeling results in EPA's August 4, 2015 NODA. The EPA is soliciting public comments on this proposed action and will consider public comments received during the comment period.

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state actions, provided that they meet the criteria of the Clean Air Act. Accordingly, this proposed action merely proposes approval of some state law as meeting federal requirements and proposes disapproval of other state law because it does not meet federal requirements; this proposed action does not propose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L.104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP does not apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the proposed rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: April 26, 2016.

Shaun L. McGrath,

Regional Administrator, Region 8.

[FR Doc. 2016–10893 Filed 5–9–16; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 227 and 252

[Docket DARS–2016–0010]

RIN 0750–AI91

Defense Federal Acquisition Regulation Supplement: Rights in Technical Data (DFARS Case 2016–D008)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Proposed rule.

SUMMARY: DoD is proposing to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to implement a section of the National Defense Authorization Act for Fiscal Year 2016 that addresses rights in technical data relating to major weapon systems, expanding application of the presumption that a commercial item has been developed entirely at private expense.

DATES: Comments on the proposed rule should be submitted in writing to the address shown below on or before July 11, 2016, to be considered in the formation of a final rule.

ADDRESSES: Submit comments identified by DFARS Case 2016–D008, using any of the following methods:

○ *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by entering "DFARS Case 2016–D008" under the heading "Enter keyword or ID" and selecting "Search." Select the link "Submit a Comment" that corresponds with "DFARS Case 2016–D008." Follow the instructions provided at the "Submit a Comment" screen. Please include your name, company name (if any), and "DFARS Case 2016–D008" on your attached document.

○ *Email: osd.dfars@mail.mil.* Include DFARS Case 2016–D008 in the subject line of the message.

○ *Fax:* 571–372–6094.

○ *Mail:* Defense Acquisition Regulations System, Attn: Ms. Amy G. Williams, OUSD(AT&L)DPAP/DARS, Room 3B941, 3060 Defense Pentagon, Washington, DC 20301–3060.

Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Ms. Amy G. Williams, telephone 571–372–6106.

SUPPLEMENTARY INFORMATION:

I. Background

DoD is proposing to revise the DFARS to implement section 813(a) of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2016 (Pub. L. 114–92) that modifies 10 U.S.C. 2321(f) to address rights in technical data relating to major weapon systems.

The validation of asserted restrictions on technical data is based on statutory requirements, codified primarily at 10 U.S.C. 2321, which are implemented in the DFARS at 227.7102–3 for commercial technical data and at 227.7103–13 for noncommercial technical data, and incorporated into individual contracts via the clause

DFARS 252.227–7037, Validation of Restrictive Markings on Technical Data, for both commercial technical data and noncommercial technical data. By longstanding policy, these requirements and procedures are adapted and applied to noncommercial computer software (see 227.7203–13 and clause 252.227–7019, Validation of Asserted Restrictions—Computer Software), but are not applied to commercial computer software.

Since 1995, these validation procedures have included specialized presumptions and procedures for commercial technical data. For discussion purposes, these specialized requirements will be referred to as the "Commercial Rule" (see 10 U.S.C. 2320(b)(1) and 2321(f)). Under the Commercial Rule, a contracting officer is required to presume that a commercial item has been developed entirely at private expense, unless shown otherwise in accordance with the procedures at 10 U.S.C. 2321(f).

Subsequently, section 802(b) of the NDAA for FY 2007, as amended by section 815(a)(2) of the NDAA for FY 2008, modified 10 U.S.C. 2321(f)(2) to establish another specialized set of procedures for technical data related to major systems (including subsystems or components thereof). For discussion purposes, this second set of specialized requirements has been referred to as the "Major Systems Rule." Under the Major Systems Rule, a contracting officer's challenge to asserted restrictions on technical data relating to a major system shall be sustained unless the contractor or subcontractor submits information demonstrating that the item was developed exclusively at private expense; except for commercially available off-the-shelf (COTS) items, which remained subject to the Commercial Rule in all cases.

The Major Systems Rule, as an exception to the Commercial Rule, was implemented in the DFARS via DFARS Case 2007–D003, which was published for comments as a proposed rule in the **Federal Register** on May 07, 2010 (75 FR 25161), and subsequently became effective via a final rule published on September 20, 2011 (76 FR 58144). As a result, the Commercial Rule was implemented for technical data at DFARS 227.7103–13(c)(1) and in the clause at DFARS 252.227–7037(b)(1), and the Major Systems Rule was implemented at 227.7103–13(c)(2) and 252.227–7037(b)(2). Additionally, the Major Systems Rule was applied to noncommercial computer software at 227.7203–13(d) and in the clause at 252.227–7019(f), although in the noncommercial computer software implementation the Major Systems Rule stands alone, rather than as an exception to the Commercial Rule, because neither the Commercial Rule, nor any element of the validation procedures overall, has been applied to commercial computer software.

Section 813(a) revised 10 U.S.C. 2321(f) to amend both the Commercial Rule and the Major Systems Rule in two primary ways:

(1) The major systems rule was narrowed to apply only to major weapon systems—essentially converting the Major Systems Rule into the Major Weapon Systems Rule.

(2) The COTS exception to the Major Systems Rule was expanded to include three additional exceptions. More specifically, the formerly COTS-only exception was expanded to include—

(i) COTS items with modifications of a type customarily available in the commercial marketplace or minor modifications made to meet Federal Government requirements;

(ii) Commercial subsystems or components of a major weapon system, if the major weapon system was acquired as a commercial item in accordance with 10 U.S.C. 2379(a); and

(iii) Components of a subsystem, if the subsystem was acquired as a commercial item in accordance with 10 U.S.C. 2379(b).

II. Discussion and Analysis

A. Implementation of the Statutory Changes for Validation of Asserted Restrictions on Technical Data

Because the DFARS already included an implementation of the Commercial Rule and Major Systems Rule, and section 813(a) revised only particular characteristics and subelements of the Major Systems Rule, the implementation of the statutory changes is relatively straightforward. More specifically, the Major Systems Rule is amended to apply only in the case of a major weapon system (see revised DFARS 227.7103–13(c)(2)(ii), and 252.227–7037(b)(2)), and the exception to the Major Systems Rule that previously referenced only COTS items, was expanded to include the three new exceptions, as well (see new DFARS 227.7103–13(c)(2)(ii)(1) through (3), and 252.227–7037(b)(2)(i)).

In addition, a minor change was made to the coverage for the Commercial Rule, which had previously referred to COTS items as always being covered by the Commercial Rule. Under the new schema, which includes four categories of items that are exceptions to the Major Weapon Systems Rule, and thereby are always governed by the Commercial Rule, it was deemed to be too complicated to refer to all four exceptions in both the coverage for the Commercial Rule and the Major Weapon Systems Rule. Accordingly, the exceptions are listed only within the Major Weapon Systems Rule, and the Commercial Rule merely cross-references that coverage as an exception to the Commercial Rule. In addition to avoiding unnecessary duplication in the coverage, this approach provides an advantage in circumstances involving an assertion regarding any type of commercial item that is not part of a major weapon system or subsystem thereof, such that there would be no need to parse through the entire Major Weapon Systems Rule only to find that the item is covered by one of the exceptions to the Major Weapon Systems Rule, and thus still covered by the Commercial Rule.

B. Application of the Revised Requirements and Procedures to Validation of Asserted Restrictions on Computer Software

DoD has made no additional edits to extend the section 813(a) construct to noncommercial computer software, and has deleted the baseline coverage of noncommercial computer software in major systems, currently at DFARS 227.7203–13(d) and 252.227–7019(f), because the purpose for the Major Weapon Systems Rule is to function as an exception to the Commercial Rule; but in the context of computer software, these validation procedures do not apply to commercial computer software, and the coverage for noncommercial computer software is concerned only with the Major Weapon Systems Rule procedures for noncommercial computer software. In the end, the application of the Major Weapon Systems Rule in those cases is extremely unlikely to reach a result that is any different from the application of the "normal" rules for noncommercial computer software. More specifically, in all cases the Government cannot initiate a challenge unless it has a reasonable basis to do so (see DFARS 227.7203–13(a) and (e)(3)(i), and 252.227–7019(d)(3) and (e)(1) for noncommercial computer software; see also 227.7103–13(a), (c)(1), and (d)(4), and 252.227–7037(d)(2) for technical data). After a challenge is initiated, both the Major Weapon Systems Rule and the "normal" validation procedures would result in the challenge being sustained unless the contractor provides information to demonstrate that the noncommercial computer software was developed exclusively at private expense.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold (SAT) and for Commercial Items, Including Commercially Available Off-the-Shelf (COTS) Items

This proposed rule does not add any new provisions or clauses or add new requirements to existing provision or clauses. Rather, when acquiring major weapon systems, it expands the circumstances relating to commerciality in which the contracting officer shall presume that development was exclusively at private expense.

IV. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is a significant regulatory action and, therefore, was subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

V. Regulatory Flexibility Act

DoD does not expect this proposed rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* However, an initial regulatory flexibility analysis has been performed and is summarized as follows:

This proposed rule was initiated to implement section 813(a) of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2016 (Pub. L. 114–92).

The objective of this rule is to reduce the requirement to respond to Government challenges of restricted rights, by expanding the applicability of the presumption regarding development exclusively at private expense in accordance with section 813(a) of the NDAA for FY 2016.

DoD cannot accurately determine the number of small entities that will be affected by this change in the regulations, because DoD does not have sufficient information about subcontract awards of subsystems and components of major weapon systems. However, DoD estimates an annual reduction of 50 prechallenge requests for information and 2 challenges of asserted technical data restrictions. DoD further estimates, based on data from the DoD FY 2014 Small Business Procurement Scorecard, that this reduction in challenges will affect about 17 small businesses (52 prechallenges/challenges × 33 percent of subcontract awards to small businesses).

The proposed rule reduces the requirement to respond to Government challenge of restricted rights. Under current regulations, the presumption regarding development exclusively at private expense does not apply to major systems or subsystems or components thereof, except for commercially available off-the-shelf items. This rule expands applicability of the presumption regarding development exclusively at private expense with regard to a major weapon system, or a subsystem or component thereof, to cover—

- A commercial subsystem or component of a major weapon system, if the major weapon system was acquired as a commercial item in accordance with DFARS subpart 234.70 (10 U.S.C. 2379(a));
- A component of a subsystem, if the subsystem was acquired as a commercial item in accordance with DFARS subpart 234.70 (10 U.S.C. 2379(b)); and
- Commercially available off-the-shelf items with modifications of a type customarily available in the commercial marketplace or minor modifications made to meet Federal Government requirements.

The classes of small entities that will be affected by this reduction are small businesses that provide any items in the above categories that are not challenged due to the new statute.

The rule does not duplicate, overlap, or conflict with any other Federal rules.

This rule reduces the burden on small entities to the maximum extent permitted by the statute.

DoD invites comments from small business concerns and other interested parties on the expected impact of this rule on small entities.

DoD will also consider comments from small entities concerning the existing regulations in subparts affected by this rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C 610 (DFARS Case 2016–D008), in correspondence.

VI. Paperwork Reduction Act

This rule affects the information collection requirements in the provisions at DFARS 252.227–7019 and 252.227–7037, currently approved under OMB Control Number 0704–0369, entitled "Defense Federal Acquisition Regulation Supplement (DFARS): Rights in Technical Data and Computer Software," in accordance with the Paperwork Reduction Act (44 U.S.C. chapter 35). The rule is expected to result in a reduction of 1,040 hours in the total estimated burden hours. DoD will submit a change request to OMB to document the reduction in burden hours at the final rule stage.

A. Based on the advice of DoD subject matter experts, DoD currently estimates approximately 500 prechallenge requests for information and approximately 20 challenges per year associated with DFARS clause 252.227–7019, Validation of Asserted Restrictions—Computer Software, and 252.227–7037, Validation of Restrictive Markings on Technical Data. Including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information, the estimated average burden to respond to a prechallenge request for information is 10 hours, and the estimated average burden to respond to each challenge, is 270 hours, resulting in a weighted average of approximately 20 hours per response.

Under current regulations, the presumption regarding development exclusively at private expense does not apply to major systems or subsystems or components thereof, except for commercially available off-the-shelf items. This rule expands applicability of the presumption regarding development exclusively at private expense with regard to a major weapon system, or a subsystem or component thereof, to cover—

- A commercial subsystem or component of a major weapon system, if the major weapon system was acquired as a commercial item in accordance with DFARS subpart 234.70 (10 U.S.C. 2379(a));
- A component of a subsystem, if the subsystem was acquired as a commercial item in accordance with DFARS subpart 234.70 (10 U.S.C. 2379(b)); and
- Commercially available off-the-shelf items with modifications of a type customarily available in the commercial marketplace or minor modifications made to meet Federal Government requirements.

Therefore, DoD estimates a reduction of about 10 percent in the estimated number of prechallenge requests for information and challenges under DFARS 252.227–7019 and 252.227–7037 as follows:

	Current requirement	Revised	Delta
Respondents	520	468	52
Responses per respondent	1	1	1
Total annual responses	520	468	52
Preparation hours per response	20	20	20
Total response burden hours	10,400	9,360	1,040

B. Request for Comments Regarding Paperwork Burden

Written comments and recommendations on the proposed information collection, including suggestions for reducing this burden, should be sent to Ms. Jasmeet Seehra at the Office of Management and Budget, Desk Officer for DoD, Room 10236, New Executive Office Building, Washington, DC 20503, or email *Jasmeet_K._Seehra@omb.eop.gov,* with a copy to the Defense Acquisition Regulations System, Attn: Ms. Amy G. Williams, OUSD(AT&L)DPAP/DARS, Room 3B941, 3060 Defense Pentagon, Washington, DC 20301–3060. Comments can be received from 30 to 60 days after the date of this proposed rule, but comments to OMB will be most useful if received by OMB within 30 days after the date of this proposed rule.

Public comments are particularly invited on: whether this collection of information is necessary for the proper performance of functions of the DFARS, and will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Defense Acquisition Regulations System, Attn: Ms. Amy G. Williams, OUSD(AT&L)DPAP/DARS, Room 3B941, 3060 Defense Pentagon, Washington, DC 20301–3060, or email *osd.dfars@mail.mil.* Include DFARS Case 2016–D008 in the subject line of the message.

List of Subjects in 48 CFR Parts 227 and 252

Government procurement.

Jennifer L. Hawes,
Editor, Defense Acquisition Regulations System.

Therefore, 48 CFR parts 227 and 252 is proposed to be amended as follows:

■ 1. The authority citation for parts 227 and 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 227—PATENT, DATA, AND COPYRIGHTS

■ 2. Amend section 227.7103–13 by—
■ a. In paragraph (c)(1), removing "commercial item, component, or process" and adding "commercial item" in its place and removing "the item, component or process" and adding "that item" in its place; and
■ b. Revising paragraphs (c)(2)(i) and (ii).

The revisions read as follows:

227.7103–13 Government right to review, verify, challenge and validate asserted restrictions.

* * * * *

(c) * * *

(2) * * *

(i) *Commercial items.* Except as provided in paragraph (c)(2)(ii) of this subsection, contracting officers shall presume that a commercial item was developed exclusively at private expense whether or not a contractor or subcontractor submits a justification in response to a challenge notice. When a challenge is warranted, a contractor's or subcontractor's failure to respond to the challenge notice cannot be the sole basis for issuing a final decision denying the validity of an asserted restriction.

(ii) *Major weapon systems.* When the contracting officer challenges an asserted restriction regarding technical data for a major weapon system or a subsystem or component thereof on the basis that the technology was not developed exclusively at private expense—

(A) The presumption in paragraph (c)(2)(i) of this subsection applies to—

(*1*) A commercial subsystem or component of a major weapon system, if the major weapon system was acquired as a commercial item in accordance with subpart 234.70 (10 U.S.C. 2379(a));

(*2*) A component of a subsystem, if the subsystem was acquired as a commercial item in accordance with subpart 234.70 (10 U.S.C. 2379(b)); and

(*3*) Any other component, if the component is a commercially available off-the-shelf item or a commercially available off-the-shelf item with modifications of a type customarily available in the commercial marketplace or minor modifications made to meet Federal Government requirements; and

(B) In all other cases, the contracting officer shall sustain the challenge unless information provided by the contractor or subcontractor demonstrates that the item was developed exclusively at private expense.

* * * * *

227.7203–13 [Amended]

■ 3. Section 227.7203–13 is amended by removing paragraph (d) and redesignating paragraphs (e), (f), and (g) as paragraphs (d), (e), and (f), respectively.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 4. Amend section 252.227–7019 by—
■ a. Removing the clause date "(SEPT 2011)" and adding "(DATE)" in its place;
■ b. Removing paragraph (f);
■ c. Redesignating paragraphs (g), (h), (i), and (j) as paragraphs (f), (g), (h), and (i), respectively;
■ d. In newly redesignated paragraph (f)(5)—
■ i. Removing "(g)(1)" and adding "(f)(1)" in its place;
■ ii. Removing "Officer will" and adding "Officer shall" in its place; and
■ iii. Removing "paragraph (f) of this clause and";
■ f. In newly redesignated paragraph (f)(6) introductory text, removing "the written explanation furnished pursuant to paragraph (f)(1) of this clause, or any other" and adding "any" in its place;

■ g. In newly redesignated paragraph (g)(1) introductory text, removing "(h)(3)" and adding "(g)(3)" in its place; and

■ h. In newly redesignated paragraph (g)(3), removing "(h)(1)" and adding "(g)(1)" in its place.

■ 5. Amend section 252.227–7037 by—

■ a. Removing the clause date "(JUN 2013)" and adding "(DATE)" in its place; and

■ b. Revising paragraphs (b)(1) and (2).

The revision reads as follows:

252.227–7037 Validation of restrictive markings on technical data.

(b) * * *

(1) *Commercial items.* (i) Except as provided in paragraph (b)(2) of this clause, the Contracting Officer will presume that the Contractor's or a subcontractor's asserted use or release restrictions with respect to a commercial item is justified on the basis that the item was developed exclusively at private expense.

(ii) The Contracting Officer will not challenge such assertions unless the Contracting Officer has information that demonstrates that the commercial item was not developed exclusively at private expense.

(2) *Major weapon systems.* In the case of a challenge to a use or release restriction that is asserted with respect to data of the Contractor or a subcontractor for a major weapon system or a subsystem or component thereof on the basis that the major weapon system, subsystem, or component was developed exclusively at private expense—

(i) The presumption in paragraph (b)(1) of this clause applies to—

(A) A commercial subsystem or component of a major weapon system, if the major weapon system was acquired as a commercial item in accordance with DFARS subpart 234.70 (10 U.S.C. 2379(a));

(B) A component of a subsystem, if the subsystem was acquired as a commercial item in accordance with DFARS subpart 234.70 (10 U.S.C. 2379(b)); and

(C) Any other component, if the component is a commercially available off-the-shelf item or a commercially available off-the-shelf item with modifications of a type customarily available in the commercial marketplace or minor modifications made to meet Federal Government requirements; and

(ii) In all other cases, the challenge to the use or release restriction will be sustained unless information provided by the Contractor or a subcontractor demonstrates that the item or process was developed exclusively at private expense.

* * * * *

[FR Doc. 2016–10827 Filed 5–9–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Part 252

[Docket DARS–2016–0016]

RIN 0750–AI94

Defense Federal Acquisition Regulation Supplement: Display of Hotline Posters (DFARS Case 2016–D018)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Proposed rule.

SUMMARY: DoD is proposing to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to consolidate the multiple hotline posters into one poster that delineates multiple reportable offenses.

DATES: Comments on the proposed rule should be submitted in writing to the address shown below on or before July 11, 2016, to be considered in the formation of a final rule.

ADDRESSES: Submit comments identified by DFARS Case 2016–D018, using any of the following methods:

○ *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by entering "DFARS Case 2016–D018" under the heading "Enter keyword or ID" and selecting "Search." Select the link "Submit a Comment" that corresponds with "DFARS Case 2016–D018." Follow the instructions provided at the "Submit a Comment" screen. Please include your name, company name (if any), and "DFARS Case 2016–D018" on your attached document.

○ *Email: osd.dfars@mail.mil.* Include DFARS Case 2016–D018 in the subject line of the message.

○ *Fax:* 571–372–6094.

○ *Mail:* Defense Acquisition Regulations System, Attn: Mr. Christopher Stiller, OUSD(AT&L)DPAP/DARS, Room 3B941, 3060 Defense Pentagon, Washington, DC 20301–3060.

Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Mr. Christopher Stiller, telephone 571–372–6176.

SUPPLEMENTARY INFORMATION:

I. Background

This rule proposes to revise the DFARS to update DFARS clause 252.203–7004, Display of Hotline Posters. This clause currently requires the display of a DoD fraud hotline poster, a separate combating trafficking in persons poster, and a whistleblower protection poster. DoD has consolidated the posters into one poster to reduce the number of posters required to be displayed and proposes updating the clause accordingly. This rule also removes the United States-only restriction for use of the DoD poster, because the human trafficking poster requires display outside the United States, even though the fraud hotline poster did not. Additionally, if the contract is funded, in whole or in part, by the Department of Homeland Security (DHS) disaster relief funds and the work is to be performed in the United States, the DHS fraud hotline poster must also be displayed. The clause also is amended to provide contact information for obtaining the DHS poster.

II. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

III. Regulatory Flexibility Act

DoD does not expect this proposed rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* However, an initial regulatory flexibility analysis has been performed and is summarized as follows:

The Defense Federal Acquisition Regulation Supplement (DFARS) clause 252.203–7004, Display of Hotline Posters, currently requires, in certain circumstance, the display of a DoD fraud hotline poster, a DoD Combatting Trafficking in Persons hotline poster, and a Department of Homeland Security (DHS) fraud hotline poster. The DoD Inspector General has consolidated the DoD hotline posters; therefore, only a one DoD poster is required.

DoD is proposing to amend the clause to clarify that only one DoD poster is required and to remove the United States-only applicability for the DoD fraud hotline poster. The rule also proposes to add contact information for obtaining the DHS hotline poster.

The clause is required for use in contracts with an estimated value greater than $5.5 million, except contracts awarded using Federal Acquisition Regulations part 12 commercial item procedures for the acquisition of commercial item. According to data available in the Federal Procurement Data System, in fiscal year (FY) 2015, DoD awarded 4,180 contracts meeting this criteria to 2,656 unique vendors, of which 1,598 (approximately 60% percent) were small businesses. DoD estimates the total number of small businesses affected by this rule to be approximately 1,920 small businesses (the total for FY 2015 plus 20 percent to accommodate subcontractor applicability).

This proposed rule does not add any new reporting, recordkeeping, or compliance requirements.

The rule does not duplicate, overlap, or conflict with any other Federal rules.

There are no known alternatives to accomplish the objectives of the proposed rule. The impact of this rule on small business is expected to be insignificant.

DoD will also consider comments from small entities concerning the existing regulations in subparts affected by this rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C 610 (DFARS Case 2016–D018), in correspondence.

IV. Paperwork Reduction Act

The rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Part 252

Government procurement.

Jennifer L. Hawes,

Editor, Defense Acquisition Regulations System.

Therefore, 48 CFR part 252 is proposed to be amended as follows:

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 1. The authority citation for part 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

■ 2. Amend section 252.203–7004 by—

■ a. Removing the clause date "(OCT 2015)" and adding "(DATE)" in its place;

■ b. Revising paragraph (b);

■ c. Removing paragraph (c);

■ d. Redesignating paragraphs (d) and (e) as paragraphs (c) and (d), respectively;

■ e. In newly redesignated paragraph (c)(1), removing "These DoD hotline posters" and adding "The DoD hotline poster" in its place;

■ f. In newly redesignated paragraph (c)(2), removing "posters are" and adding "poster is" in its place and removing "(d)(1)" and adding " (c)(1)" in its place; and

■ g. In newly designated paragraph (d), removing "(e)" and adding "(d)" in its place.

The revision reads as follows:

252.203–7004 Display of Hotline Posters.

* * * * *

(b) *Display of hotline poster(s).* (1) The Contractor shall display prominently the DoD fraud, waste, and abuse hotline poster, in effect at time of contract award prepared by the DoD Office of the Inspector General, in common work areas within business segments performing work under DoD contracts.

(2) If the contract is funded, in whole or in part, by Department of Homeland Security (DHS) disaster relief funds and the work is to be performed in the United States the DHS fraud hotline poster shall be displayed in addition to the DoD hotline poster. If a display of a DHS fraud hotline poster is required, the Contractor may obtain such poster from: DHS Office of Inspector General/ MAIL STOP 0305, Attn: Office of Investigations—Hotline, 245 Murray Lane SW., Washington, DC 20528–0305, or also available via the internet at *https://www.oig.dhs.gov/assets/Hotline/DHS_OIG_Hotline-optimized.jpg.*

* * * * *

[FR Doc. 2016–10829 Filed 5–9–16; 8:45 am]

BILLING CODE 5001–06–P

Notices

Federal Register
Vol. 81, No. 90
Tuesday, May 10, 2016

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

AGENCY FOR INTERNATIONAL DEVELOPMENT

Board for International Food and Agricultural Development; Notice of Meeting

Pursuant to the Federal Advisory Committee Act, notice is hereby given of the public meeting of the Board for International Food and Agricultural Development (BIFAD). The meeting will be held from 8:30 a.m. to 12:00 p.m. EDT on Friday, May 20, 2016, at the Center Ballroom, Alumni-Foundation Event Center, North Carolina Agricultural & Technical State University, 200 North Benbow Road, Greensboro, NC 27411. The meeting will be streamed live on the Internet. The link to the global live stream is on BIFAD's home page: *http://www.usaid.gov/bifad*.

The central theme of this public meeting will be *Collaboration: Leadership, Innovation and Sustainable Technology to Meet the Demands of Global Agriculture*. Dr. Brady Deaton, BIFAD Chair, will preside over the public business meeting, which will begin promptly at 8:30 a.m. EDT with opening remarks. At this meeting, the Board will address old and new business and hear updates from USAID, the university community, and other experts on the role of technology and innovation in meeting the demands of feeding the world's population.

Starting at 9:15 a.m., BIFAD will hear from the first panel, moderated by Dr. Valerie Giddings, Interim Associate Dean for research in the School of Agriculture and Environmental Sciences, on *N.C. A&T Leadership in International Agricultural Innovation*. Panelists include: Dr. Manuel Reyes, Professor in the Department of Natural Resources and Environmental Design in the School of Agriculture and Environmental Sciences; Dr. Osei Yeboah, Professor and Interim Director of the Leonard C. Cooper, Jr. International Trade Center; Dr. Anthony Yeboah, Professor and Chairperson of the Department of Agribusiness, Applied Economics and Agriscience Education.

Starting at 10:30 a.m., the second panel will present on *Sustainable Technology Development to Meet Demands of Global Agriculture*. Moderating this panel is Vice President of Agricultural Biotech Scott Johnson. Panelists include Dr. Nic Bate, Group Leader for Agronomic Traits, Syngenta, Dr. Gregory Kelly, COO, SoBran BioScience, and Kathy Flores, General Manager, Purdue Farms Specialty Crops.

At 11:30 a.m., Chairman Deaton will moderate a half-hour public comment period. At 12:00 p.m. EDT, Dr. Deaton will make closing remarks and adjourn the public meeting.

Those wishing to attend the meeting or obtain additional information about BIFAD should contact Clara Cohen, Interim Designated Federal Officer for BIFAD in the Bureau for Food Security at USAID. Interested persons may write to her in care of the U.S. Agency for International Development, Ronald Reagan Building, Bureau for Food Security, 1300 Pennsylvania Avenue NW., Washington, DC 20523–2110 or telephone her at (202) 712–0119.

Clara Cohen,

USAID Interim Designated Federal Officer for BIFAD, Bureau for Food Security, U.S. Agency for International Development.

[FR Doc. 2016–10934 Filed 5–9–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

Submission for OMB Review; Comment Request

May 4, 2016.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding (1) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by June 9, 2016 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725—17th Street NW., Washington, DC 20502. Commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Food Safety and Inspection Service

Title: Importation and Transportation of Meat, Poultry and Egg Products.

OMB Control Number: 0583–0094.

Summary of Collection: The Food Safety and Inspection Service (FSIS) has been delegated the authority to exercise the functions of the Secretary as provided in the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.)* and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*), and the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031, *et seq.*) These statutes mandate that FSIS protect the public by ensuring that meat, poultry, and egg products are safe, wholesome, unadulterated, and properly labeled and packaged. Meat and poultry products not marked with the mark of inspection and shipped from one official establishment to another for further processing must be transported under FSIS seal to prevent such unmarked product for entering into commerce. To track product shipped under seal, FSIS requires shipping establishments to complete a form that identifies the type, amount, and weight of the product. Foreign countries that wish to export meat, poultry, and egg products to the United States must establish eligibility to do so by putting in place inspection systems that are "equivalent to" the U.S. inspection system and by annually certifying that they continue to do so.

Need and Use of the Information: FSIS will collect information using form 7350–1, Request and Notice of Shipment of Sealed Meat/Poultry. FSIS will collect the name, number, method of shipping, and destination of product, type and description of product to be shipped, reason for shipping product, and a signature. Meat, poultry, and egg products intended for importation into the U.S. must be accompanied by an inspection certificate signed by an official of the foreign government responsible for the inspection and certification of the product.

Description of Respondents: Business or other for-profit.

Number of Respondents: 136.

Frequency of Responses: Recordkeeping; Reporting: On occasion.

Total Burden Hours: 4,026.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2016–10933 Filed 5–9–16; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF AGRICULTURE

Rural Housing Service

U.S. Department of Agriculture Multi-Family Housing Program 2016 Industry Forums—Open Teleconference and/or Web Conference Meetings

AGENCY: Rural Housing Service, USDA.

ACTION: Announcement of meetings.

SUMMARY: This Notice announces a series of Teleconferences and/or Web Conference Meetings regarding the U.S. Department of Agriculture (USDA), Multi-Family Housing program. The Teleconference and/or Web Conference Meetings will be scheduled on a quarterly basis, but may be held more often at the Agency's discretion. This Notice also outlines suggested discussion topics for the meetings and is intended to notify the general public of their opportunity to participate in the Teleconference and/or Web Conference Meetings.

DATES: See **SUPPLEMENTARY INFORMATION** section for dates.

FOR FURTHER INFORMATION CONTACT: Timothy James, Loan and Finance Analyst, Multi-Family Housing, (919) 873–2056, or email *timothy.james@wdc.usda.gov.*

SUPPLEMENTARY INFORMATION: The objectives of this series of teleconferences are as follows:

- Enhance the effectiveness of the Multi-Family Housing program.
- Establish a two-way communications forum to update industry participants and Rural Housing Service (RHS) staff.
- Enhance RHS' awareness of issues that impact the Multi-Family Housing program.
- Increase transparency and accountability in the Multi-Family Housing program.

Topics to be discussed could include, but will not be limited to, the following:

- Updates on USDA Multi-Family Housing program activities.
- Perspectives on the Multi-Family Housing Notice of Funds Availability processes.
- Comments on multi-family transaction processes.
- Comments on particular servicing-related activities of interest at that time.

DATES: Teleconference and/or Web Conference Meetings are scheduled to occur quarterly during 2016. The dates and times for the Teleconference and/or Web Conference Meetings will be announced via email to parties registered as described below.

REGISTRATION: Any member of the public wishing to register for the meetings and obtain the call-in number, access code, web link and other information for any of the public Teleconference and/or Web Conference Meetings may contact Timothy James, Loan and Finance Analyst, Multi-Family Housing, (919) 873–2056, or email *timothy.james@wdc.usda.gov.* The public will provide their name, title, Agency/company name, address, telephone numbers and email address. Persons who are already registered do not need to register again. Individuals who plan to participate and need reasonable accommodations or language translation assistance should inform Timothy James within 10 business days in advance of the meeting date. The Teleconference and/or Web Conference Meetings will be in compliance with Section 508 of the Rehabilitation Act.

Non-Discrimination Statement

In accordance with Federal civil rights law and U.S. Department of Agriculture (USDA) civil rights regulations and policies, the USDA, its Agencies, offices, and employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Persons with disabilities who require alternative means of communication for program information (*e.g.,* Braille, large print, audiotape, American Sign Language, etc.) should contact the responsible Agency or USDA's TARGET Center at (202) 720–2600 (voice and TTY) or contact USDA through the Federal Relay Service at (800) 877–8339. Additionally, program information may be made available in languages other than English.

To file a program discrimination complaint, complete the USDA Program Discrimination Complaint Form, AD–3027, found online at *http://www.ascr.usda.gov/complaint_filing_cust.html* and at any USDA office or write a letter addressed to USDA and provide in the letter all of the information requested in the form. To request a copy of the complaint form, call (866) 632–9992. Submit your completed form or letter to USDA by:

(1) By *mail:* U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW., Washington DC 20250–9410;

(2) *Fax:* (202) 690–7442; or

(3) *Email: program.intake@usda.gov.*

USDA is an equal opportunity provider and employer.

Dated: May 3, 2016.

Tony Hernandez,

Administrator, Rural Housing Service.

[FR Doc. 2016–10861 Filed 5–9–16; 8:45 am]

BILLING CODE 3410–XV–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Wisconsin Advisory Committee To Discuss Preparations for a Hearing on Hate Crimes in the State

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Wisconsin Advisory Committee (Committee) will hold a meeting on Thursday, June 2, 2016, at 12:00 p.m. CDT for the purpose of preparing for a hearing on hate crime in the state.

This meeting is open to the public through the following toll-free call-in number: 888–438–5519, conference ID: 4977249. Any interested member of the public may call this number and listen to the meeting. The conference call operator will ask callers to identify themselves, the organization they are affiliated with (if any), and an email address prior to placing callers into the conference room. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–977–8339 and providing the Service with the conference call number and conference ID number.

Member of the public are invited to make statements to the Committee during the scheduled open comment period. In addition, members of the public may submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be mailed to the Regional Programs Unit, U.S. Commission on Civil Rights, 55 W. Monroe St., Suite 410, Chicago, IL 60615. They may also be faxed to the Commission at (312) 353–8324, or emailed to Carolyn Allen at *callen@usccr.gov.* Persons who desire additional information may contact the Regional Programs Unit at (312) 353–8311.

Records and documents discussed during the meeting will be available for public viewing prior to and after the meeting at *https://database.faca.gov/committee/meetings.aspx?cid=282.* Click on the "Meeting Details" and "Documents" links to download. Records generated from this meeting may also be inspected and reproduced at the Regional Programs Unit, as they become available, both before and after the meeting. Persons interested in the work of this Committee are directed to the Commission's Web site, *http://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda:

I. Welcome and Introductions—Naheed Bleecker, Chair
II. Hearing Preparation: Hate Crimes and Civil Rights in Wisconsin
  - Scope
  - Panelists
  - Logistics (schedule, location, date)
III. Open Comment—Public Participation
IV. Adjournment

DATES: The meeting will be held on Thursday, June 2, 2016, at 12:00 p.m. CDT.

Public Call Information:
Dial: 888–438–5519
Conference ID: 4977249

FOR FURTHER INFORMATION CONTACT: Melissa Wojnaroski, DFO, at 312–353–8311 or *mwojnaroski@usccr.gov.*

Dated: May 5, 2016.

David Mussatt,

Chief, Regional Programs Unit.

[FR Doc. 2016–10965 Filed 5–9–16; 8:45 am]

BILLING CODE 6335–01–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Missouri Advisory Committee To Discuss Approval of a Draft Report Resulting From Testimony Received Regarding Civil Rights and Police/Community Interactions in the State

AGENCY: U.S. Commission on Civil Rights.

ACTION: Notice of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Missouri Advisory Committee (Committee) will hold a meeting on Tuesday May 31, 2016, at 2:30pm CDT for the purpose of discussing oral and written testimony received during two public meetings focused on civil rights and police and community interactions in Missouri. Themes and findings discussed during this meeting will form the basis of a report to be issued to the Commission on this topic.

Members of the public can listen to the discussion. This meeting is available to the public through the following toll-free call-in number: 888–329–8862, conference ID: 4738573. Any interested member of the public may call this number and listen to the meeting. Callers can expect to incur regular charges for calls they initiate over wireless lines according to their wireless plan, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–977–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are also entitled to submit written comments; the comments must be received in the regional office within thirty days following the meeting. Written comments may be mailed to the Midwestern Regional Office, U.S. Commission on Civil Rights, 55 W. Monroe St., Suite 410, Chicago, IL 60615. They may also be faxed to the Commission at (312) 353–8324, or emailed to Corrine Sanders at *csanders@usccr.gov.* Persons who desire additional information may contact the Midwestern Regional Office at (312) 353–8311.

Records generated from this meeting may be inspected and reproduced at the Midwestern Regional Office, as they become available, both before and after the meeting. Records of the meeting will be available at *https://database.faca.gov/committee/meetings.aspx?cid=258.* Click on "meeting details" and "documents" to download. Persons interested in the work of this Committee are directed to the Commission's Web site, *http://www.usccr.gov,* or may contact the Midwestern Regional Office at the above email or street address.

Agenda:

Welcome and Introductions

Committee Discussion: Draft report resulting from Committee hearings on Civil Rights and Police/Community Relations in Missouri. (February 23, 2015 St. Louis; August 20, 2015 Kansas City)

Open Comment

Recommendations and Next Steps

DATES: The meeting will be held on Tuesday, May 31, 2016, at 2:30 p.m. CDT.

Public Call Information:

Dial: 888–329–8862

Conference ID: 4738573

FOR FURTHER INFORMATION CONTACT: Melissa Wojnaroski, DFO, at 312–353–8311 or *mwojnaroski@usccr.gov.*

Dated: May 5, 2016.

David Mussatt,

Chief, Regional Programs Unit.

[FR Doc. 2016–10962 Filed 5–9–16; 8:45 am]

BILLING CODE 6335–01–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Michigan Advisory Committee To Hear Testimony Regarding the Civil Rights Impact of Civil Forfeiture Practices in the State

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Michigan Advisory Committee (Committee) will hold a meeting on Monday May 23, 2016, at 3:00 p.m. EDT for the purpose of hearing testimony regarding the civil rights impact of civil asset forfeiture in the State.

This meeting will take place via web-conference and is available to the public through the following toll-free call-in number: 888–572–7034, conference ID: 1448776. Any interested member of the public may call this number and listen to the meeting (audio only). Members of the public may register for access to the online portion of the meeting (visual) at the following link: *https://cc.readytalk.com/cc/s/registrations/new?cid=1xloulorqep3.* An open comment period will be provided to allow members of the public to make a statement at the end of the meeting. The conference call operator will ask callers to identify themselves, the organization they are affiliated with (if any), and an email address prior to placing callers into the conference room. Callers can expect to incur regular charges for calls they initiate over wireless lines according to their wireless plan, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–977–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are also entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be mailed to the Regional Programs Unit, U.S. Commission on Civil Rights, 55 W. Monroe St., Suite 410, Chicago, IL 60615. They may also be faxed to the Commission at (312) 353–8324, or emailed to Carolyn Allen at *callen@usccr.gov.* Persons who desire additional information may contact the Regional Programs Unit at (312) 353–8311.

Records and documents discussed during the meeting will be available for public viewing prior to and after the meeting at *http://facadatabase.gov/committee/meetings.aspx?cid=255.* Click on the "Meeting Details" and "Documents" links to download. Records generated from this meeting may also be inspected and reproduced at the Regional Programs Unit, as they become available, both before and after the meeting. Persons interested in the work of this Committee are directed to the Commission's Web site, *http://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda

3:00–3:05 p.m. Welcome and Introductions—*Donna Budnick, Chair*

3:05–4:00 p.m. Panel: Civil Rights Impact of Civil Forfeiture Practices in Michigan

- Brian Kelly, Associate Professor of Economics, Seattle University
- Dick Carpenter, Institute for Justice
- Rebecca Vallas, Center for American Progress
- Stefan Cassella, Asset Forfeiture Law

4:00–4:15 p.m. Committee Questions
4:15–4:30 p.m. Open Comment
4:30 p.m. Adjournment

DATES: The meeting will be held on Monday, May 23, 2016, at 3:00 p.m. EDT.

Public Call Information

Dial: 888–572–7034.
Conference ID: 1448776.

FOR FURTHER INFORMATION CONTACT: Melissa Wojnaroski at *mwojnaroski@usccr.gov* or 312–353–8311.

Dated: May 5, 2016.

David Mussatt,
Chief, Regional Programs Unit.

[FR Doc. 2016–10963 Filed 5–9–16; 8:45 am]

BILLING CODE 6335–01–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Michigan Advisory Committee To Hear Testimony Regarding the Civil Rights Impact of Civil Forfeiture Practices in the State

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Michigan Advisory Committee (Committee) will hold a meeting on Thursday May 26, 2016, from 9:00 a.m.–3:45 p.m. EDT for the purpose of hearing testimony regarding the civil rights impact of civil asset forfeiture in the State. Of concern to the Committee is the extent to which law enforcement seizure of property believed to be connected to illegal activity may have a disparate impact on the basis of race, color, or other federally protected category.

This meeting will take place at the Michigan Department of Transportation, Office of Aeronautics Auditorium, 2700 Port Lansing Rd., Lansing, MI 48906. This meeting is free and open to the public. An open forum period will be provided to allow members of the public to make a statement at the end of the morning and afternoon sessions. Individuals with disabilities requiring reasonable accommodations should contact the Regional Programs Unit at 312–353–8311 ten days prior to the meeting to make appropriate arrangements.

Members of the public are also entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be mailed to the Regional Programs Unit, U.S. Commission on Civil Rights, 55 W. Monroe St., Suite 410, Chicago, IL 60615. They may also be faxed to the Commission at (312) 353–8324, or emailed to Carolyn Allen at *callen@usccr.gov.* Persons who desire additional information may contact the Regional Programs Unit at (312) 353–8311.

Records and documents discussed during the meeting will be available for public viewing prior to and after the meeting at *http://facadatabase.gov/committee/meetings.aspx?cid=255.* Click on the "Meeting Details" and "Documents" links to download. Records generated from this meeting may also be inspected and reproduced at the Regional Programs Unit, as they become available, both before and after the meeting. Persons interested in the work of this Committee are directed to the Commission's Web site, *http://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda

○ Opening Remarks and Introductions (9:00 a.m.–9:10 a.m.)
  - Panel 1: (9:10 a.m.–10:20 a.m.) Attorneys

  - Panel 2: (10:30 a.m.–11:40 a.m.) Legislators
  - Open Forum (11:40 a.m.–12:00 p.m.)
- ○ Break (12:00 p.m.–1:30 p.m.)
  - Panel 3: (1:30 p.m.–2:45 p.m.) Law Enforcement
  - Open Forum (3:00 p.m.–3:30 p.m.)
- ○ Closing Remarks (3:30 p.m.–3:45 p.m.)

DATES: The meeting will be held on Thursday, May 26, 2016, at 9:00 a.m. EDT.

FOR FURTHER INFORMATION CONTACT: Melissa Wojnaroski at *mwojnaroski@usccr.gov* or 312–353–8311.

Dated: May 5, 2016.

David Mussatt,

Chief, Regional Programs Unit.

[FR Doc. 2016–10964 Filed 5–9–16; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

In the Matter of: Ali Khanaman Mohammadi, 7 Bascom Street, Irvine, CA 92612; Order Denying Export Privileges

On August 25, 2015, in the U.S. District Court for the Northern District of Illinois, Ali Khanaman Mohammadi ("Mohammadi") was convicted of violating the International Emergency Economic Powers Act (50 U.S.C. 1701, *et seq.* (2006 & Supp. IV 2010)) ("IEEPA"). Specifically, Mohammadi knowingly and willfully conspired with others known and unknown to export goods and technology, namely, one Series 446 Rate Integrating Gyroscope, Model LC08, from the United States to Iran. Mohammadi was sentenced to five years of probation, a special assessment of $100.00 and a criminal fine of $2,000.

Section 766.25 of the Export Administration Regulations ("EAR" or "Regulations")[1] provides, in pertinent part, that "[t]he Director of the Office of Exporter Services, in consultation with the Director of the Office of Export Enforcement, may deny the export privileges of any person who has been convicted of a violation of the Export Administration Act ("EAA"), the EAR, or any order, license or authorization issued thereunder; any regulation, license, or order issued under the International Emergency Economic Powers Act (50 U.S.C. 1701–1706); 18 U.S.C. 793, 794 or 798; section 4(b) of the Internal Security Act of 1950 (50 U.S.C. 783(b)), or section 38 of the Arms Export Control Act (22 U.S.C. 2778)." 15 CFR 766.25(a); *see also* Section 11(h) of the EAA, 50 U.S.C. 4610(h). The denial of export privileges under this provision may be for a period of up to 10 years from the date of the conviction. 15 CFR 766.25(d); *see also* 50 U.S.C. 4610(h). In addition, Section 750.8 of the Regulations states that the Bureau of Industry and Security's Office of Exporter Services may revoke any Bureau of Industry and Security ("BIS") licenses previously issued in which the person had an interest in at the time of his conviction.

BIS has received notice of Mohammadi's conviction for violating IEEPA, and in accordance with Section 766.25 of the Regulations, BIS has provided notice and an opportunity for Mohammadi to make a written submission to BIS. BIS has not received a submission from Mohammadi.

Based upon my review and consultations with BIS's Office of Export Enforcement, including its Director, and the facts available to BIS, I have decided to deny Mohammadi's export privileges under the Regulations for a period of 10 years from the date of Mohammadi's conviction. I have also decided to revoke all licenses issued pursuant to the Act or Regulations in which Mohammadi had an interest at the time of his conviction.

Accordingly, it is hereby *ordered:*

First, from the date of this Order until August 25, 2025, Ali Khanaman Mohammadi, with a last known address of 7 Bascom Street, Irvine, CA 92612, and when acting for or on his behalf, his successors, assigns, employees, agents or representatives (the "Denied Person"), may not, directly or indirectly, participate in any way in any transaction involving any commodity, software or technology (hereinafter collectively referred to as "item") exported or to be exported from the United States that is subject to the Regulations, including, but not limited to:

A. Applying for, obtaining, or using any license, License Exception, or export control document;

B. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or in any other activity subject to the Regulations; or

C. Benefitting in any way from any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or in any other activity subject to the Regulations.

Second, no person may, directly or indirectly, do any of the following:

A. Export or reexport to or on behalf of the Denied Person any item subject to the Regulations;

B. Take any action that facilitates the acquisition or attempted acquisition by the Denied Person of the ownership, possession, or control of any item subject to the Regulations that has been or will be exported from the United States, including financing or other support activities related to a transaction whereby the Denied Person acquires or attempts to acquire such ownership, possession or control;

C. Take any action to acquire from or to facilitate the acquisition or attempted acquisition from the Denied Person of any item subject to the Regulations that has been exported from the United States;

D. Obtain from the Denied Person in the United States any item subject to the Regulations with knowledge or reason to know that the item will be, or is intended to be, exported from the United States; or

E. Engage in any transaction to service any item subject to the Regulations that has been or will be exported from the United States and which is owned, possessed or controlled by the Denied Person, or service any item, of whatever origin, that is owned, possessed or controlled by the Denied Person if such service involves the use of any item subject to the Regulations that has been or will be exported from the United States. For purposes of this paragraph, servicing means installation, maintenance, repair, modification or testing.

Third, after notice and opportunity for comment as provided in Section 766.23 of the Regulations, any other person, firm, corporation, or business organization related to Mohammadi by ownership, control, position of responsibility, affiliation, or other connection in the conduct of trade or business may also be made subject to the provisions of this Order in order to prevent evasion of this Order.

Fourth, in accordance with Part 756 of the Regulations, Mohammadi may file an appeal of this Order with the Under Secretary of Commerce for Industry and

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[1] 50 U.S.C. 4601–4623 (Supp. III 2015) (available at *http://uscode.house.gov*). Since August 21, 2001, the Act has been in lapse and the President, through Executive Order 13222 of August 17, 2001 (3 CFR, 2001 Comp. 783 (2002)), which has been extended by successive Presidential Notices, the most recent being that of August 7, 2015 (80 FR 48,233 (Aug. 11, 2015)), has continued the Regulations in effect under the International Emergency Economic Powers Act (50 U.S.C. 1701, *et seq.* (2006 & Supp. IV 2010)).

Security. The appeal must be filed within 45 days from the date of this Order and must comply with the provisions of Part 756 of the Regulations.

Fifth, a copy of this Order shall be delivered to the Mohammadi. This Order shall be published in the **Federal Register**.

Sixth, this Order is effective immediately and shall remain in effect until August 25, 2025.

Issued this 4th day of May, 2016.

Karen H. Nies-Vogel,

Director, Office of Exporter Services.

[FR Doc. 2016–10927 Filed 5–9–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–489–815]

Light-Walled Rectangular Pipe and Tube From Turkey: Final Results of Antidumping Duty Administrative Review; 2014–2015

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On February 12, 2016, the Department of Commerce (the Department) published the preliminary results of the administrative review of the antidumping duty order on light-walled rectangular pipe and tube from Turkey.[1] The review covers Agir Haddecilik A.Ş. (Haddecilik). The period of review (POR) is May 1, 2014, through April 30, 2015. We invited interested parties to comment on our *Preliminary Results.* No parties commented, and our final results remain unchanged from our *Preliminary Results.* The final results are listed in the section entitled "Final Results of Review," below.

DATES: *Effective Date:* May 10, 2016.

FOR FURTHER INFORMATION CONTACT: Mark Flessner or Robert M. James, AD/CVD Operations Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–6312 or (202) 482–0649, respectively.

SUPPLEMENTARY INFORMATION:

Background

On February 12, 2016, the Department published the *Preliminary Results* of this review in the **Federal Register**. We invited parties to comment on the *Preliminary Results.* No party commented, nor did any party request a hearing.

Tolling of Deadline

As explained in the memorandum from the Acting Assistant Secretary for Enforcement & Compliance, the Department has exercised its discretion to toll all administrative deadlines due to the recent closure of the Federal Government. All deadlines in this segment of the proceeding have been extended by four business days. The revised deadline for the final results of this review is now June 13, 2016.[2]

Scope of the Order

The merchandise subject to this order[3] is certain welded carbon-quality light-walled steel pipe and tube, of rectangular (including square) cross section, having a wall thickness of less than 4 mm.[4]

Final Results of Review

As a result of our review, we determine the following weighted-average dumping margin exists for the period May 1, 2014, through April 30, 2015:

Producer/exporter	Weighted-average margin (percentage)
Agir Haddecilik A.Ş.	0.00

Assessment

The Department shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries, in accordance with 19 CFR 351.212(b)(1). The Department intends to issue appropriate assessment instructions for the companies subject to this review to CBP 15 days after the date of publication of these final results.

Haddecilik's weighted-average dumping margin in these final results is zero percent. Therefore, we will instruct CBP to liquidate all appropriate entries without regard to antidumping duties.

Cash Deposit Requirements

The following cash deposit rates will be effective upon publication of the final results of this administrative review for all shipments of light-walled rectangular pipe and tube from Turkey entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by section 751(a)(2)(C) of the Tariff Act of 1930, as amended (the Act): (1) For Agir Haddecilik A.Ş., the cash deposit rate will be equal to the weighted-average dumping margin listed above; (2) for previously reviewed or investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment of this proceeding in which that manufacturer or exporter participated; (3) if the exporter is not a firm covered in this review, a prior review, or the original less-than-fair-value (LTFV) investigation, but the producer is, the cash deposit rate will be the rate established for the most recently completed segment of this proceeding for the producer of the merchandise; and (4) if neither the exporter nor the producer is a firm covered in this review, any previous review, or the original investigation, the cash deposit rate will be 27.04 percent *ad valorem,* the "all others" rate established in the LTFV investigation. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Administrative Protective Order Notification to Interested Parties

This notice serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which

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[1] *See Light-Walled Rectangular Pipe and Tube From Turkey; Preliminary Results of Antidumping Duty Administrative Review; 2014–2015,* 81 FR 7503 (February 12, 2016) (*Preliminary Results*).

[2] *See* Memorandum to the Record from Ron Lorentzen, Acting A/S for Enforcement & Compliance, regarding "Tolling of Administrative Deadlines As a Result of the Government Closure During Snowstorm Jonas," dated January 27, 2016; see also *Preliminary Results.*

[3] *See Notice of Antidumping Duty Order: Light-Walled Rectangular Pipe and Tube From Turkey,* 73 FR 31065 (May 30, 2008).

[4] For a full description of the scope of the order, *see* the memorandum from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Paul Piquado, Assistant Secretary for Enforcement and Compliance, entitled "Light-Walled Rectangular Pipe and Tube from Turkey: Decision Memorandum for the Preliminary Results of Antidumping Duty Administrative Review; 2014–2015," dated February 5, 2016.

continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

This administrative review and notice are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.213(h)(1).

Dated: May 3, 2016.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2016–11032 Filed 5–9–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–86]

Welded Stainless Pressure Pipe From India: Affirmative Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce ("Department") preliminarily determines that Welded Stainless Pressure Pipe from India ("WSPP") is being, or is likely to be, sold in the United States at less than fair value ("LTFV"), as provided in section 733(b) of the Tariff Act of 1930, as amended ("the Act"). The period of investigation ("POI") is July 1, 2014, through June 30, 2015. The estimated weighted-average dumping margins of sales at LTFV are shown in the "Preliminary Determination" section of this notice. Interested parties are invited to comment on this preliminary determination.

DATES: *Effective Date:* May 10, 2016.

FOR FURTHER INFORMATION CONTACT: James Terpstra, or Alex Rosen, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–3965, or (202) 482–7814, respectively.

SUPPLEMENTARY INFORMATION:

Background

The Department published the notice of initiation of this investigation on October 27, 2015.[1] For a complete description of the events that followed the initiation of this investigation, see the memorandum that is dated concurrently with this determination and hereby adopted by this notice.[2] A list of topics included in the Preliminary Decision Memorandum is included as Appendix II to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System ("ACCESS"). ACCESS is available to registered users at *https://access.trade.gov,* and to all parties in the Central Records Unit, room B8024 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be found at *http://enforcement.trade.gov/frn/.* The signed Preliminary Decision Memorandum and the electronic version of the Preliminary Decision Memorandum are identical in content.

As explained in the memorandum from the Acting Assistant Secretary for Enforcement and Compliance, the Department exercised its discretion to toll deadlines as a result of the closure of the Federal Government for Snowstorm Jonas.[3] All deadlines in this segment of the proceeding have been extended by four business days. Furthermore, on March 3, 2016, based upon a request from Petitioners, the Department postponed the time period for the preliminary determination of this investigation by 40 days, to May 3, 2016, in accordance with section 733(c)(1)(B) of the Act and 19 CFR 351.205(f)(1).[4]

Scope of the Investigation

The product covered by this investigation is circular welded austenitic stainless pressure pipe not greater than 14 inches in outside diameter, from India. For a full description of the scope of this investigation, *see* the "Scope of the Investigation," in Appendix I.

Scope Comments

In accordance with the preamble to the Department's regulations,[5] the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage (*i.e.,* "scope").[6] No party commented on the scope of the investigation as it appeared in the *Initiation Notice,* and the scope language is unchanged for this preliminary determination.

Methodology

The Department is conducting this investigation in accordance with section 731 of the Act. For the two mandatory respondents Steamline Industries Ltd ("Steamline") and Sunrise Stainless Pvt. Ltd ("Sunrise"), we calculated export price (EP) and constructed export price ("CEP") in accordance with section 772 of the Act, and normal value ("NV") in accordance with section 773 of the Act. For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum.

All-Others Rate

Section 735(c)(5)(A) of the Act provides that the estimated all-others rate shall be an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero or *de minimis* margins, and any margins determined entirely under section 776 of the Act. Because we calculated a *de minimis* weighted-average dumping margin for Sunrise Stainless Pvt. Ltd. ("Sunrise"), we based the all-others rate on the margin calculated for Steamline Industries Ltd. ("Steamline"), the other mandatory respondent in this investigation.

Preliminary Determination

The Department preliminarily determines that the following estimated weighted-average dumping margins exist:

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[1] *See Welded Stainless Pressure Pipe from India: Initiation of Antidumping Duty Investigation,* 80 FR 65696 (October 27, 2015) ("*Initiation Notice*").

[2] *See* Memorandum from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Paul Piquado, Assistant Secretary for Enforcement and Compliance, "Decision Memorandum for the Preliminary Determination in the Antidumping Duty Investigation of Welded Stainless Pressure Pipe from India" ("Preliminary Decision Memorandum"), dated concurrently with this notice.

[3] *See* Memorandum to the file from Ron Lorentzen, Acting Assistant Secretary for Enforcement and Compliance, "Tolling of Administrative Deadlines as a Result of the Government Closure during Snowstorm 'Jonas,'" dated January 27, 2016.

[4] *See Welded Stainless Pressure Pipe from India: Postponement of Preliminary Determination of Antidumping Duty Investigation,* 81 FR 11179 (March 3, 2016).

[5] *See Antidumping Duties; Countervailing Duties,* 62 FR 27296, 27323 (May 19, 1997).

[6] *See Initiation Notice,* 80 FR at 65696.

Exporter/producer	Weighted-average margin (percent)
Steamline Industries Ltd.	18.90
Sunrise Stainless Pvt. Ltd. and Sun Mark Stainless Pvt. Ltd. (collectively, "Sunrise") [7]	*1.91
All Others	18.90

* (*de minimis*)

Suspension of Liquidation

In accordance with section 733(d)(2) of the Act, we will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of all entries of WSPP from India, with the exception of exports from Sunrise, as described in the scope of the investigation section entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. Pursuant to 19 CFR 351.205(d), we will instruct CBP to require a cash deposit equal to the weighted-average amount by which the NV exceeds CEP, as indicated in the chart above [8] adjusted where appropriate for export subsidies, as follows: the rate for Steamline, when adjusted for export subsidies, is 16.90 percent; the rate for all others producers or exporters, when adjusted for export subsidies, is also 16.90 percent. These suspension of liquidation instructions will remain in effect until further notice.

Disclosure and Public Comment

We will disclose the calculations performed to interested parties in this proceeding within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b). Interested parties are invited to comment on this preliminary determination. Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the final verification report is issued in this proceeding, and rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than five days after the deadline date for case briefs.[9] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce. All documents must be filed electronically using ACCESS. An electronically-filed request must be received successfully in its entirety by ACCESS by 5:00 p.m. Eastern Time, within 30 days after the date of publication of this notice.[10] Requests should contain the party's name, address, and telephone number, the number of participants, and a list of the issues to be discussed. If a request for a hearing is made, the Department intends to hold the hearing at the U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230, at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

Verification

As provided in section 782(i) of the Act, we intend to verify information relied upon in making our final determination.

Postponement of Final Determination and Extension of Provisional Measures

Section 735(a)(2) of the Act provides that a final determination may be postponed until not later than 135 days after the date of the publication of the preliminary determination if, in the event of an affirmative preliminary determination, a request for such postponement is made by exporters who account for a significant proportion of exports of the subject merchandise, or in the event of a negative preliminary determination, a request for such postponement is made by Petitioners. 19 CFR 351.210(e)(2) requires that requests by respondents for postponement of a final antidumping determination be accompanied by a request for extension of provisional measures from a four-month period to a period not more than six months in duration.

On April 28, 2016, pursuant to 19 CFR 351.210(b) and (e), Sunrise requested that, contingent upon an affirmative preliminary determination of sales at LTFV, the Department postpone the final determination and that provisional measures be extended to a period not to exceed six months.[11]

In accordance with section 735(a)(2)(A) of the Act and 19 CFR 351.210(b)(2)(ii), because (1) our preliminary determination is affirmative; (2) the requesting exporter accounts for a significant proportion of exports of the subject merchandise; and (3) no compelling reasons for denial exist, we are postponing the final determination and extending the provisional measures from a four-month period to a period not greater than six months. Accordingly, we will make our final determination no later than 135 days after the date of publication of this preliminary determination, pursuant to section 735(a)(2) of the Act.[12]

International Trade Commission ("ITC") Notification

In accordance with section 733(f) of the Act, we will notify the ITC of our preliminary affirmative determination of sales at LTFV. Because the preliminary determination in this proceeding is affirmative, section 735(b)(2) of the Act requires that the ITC make its final determination whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports of WSPP from India before the later of 120 days after the date of this preliminary determination or 45 days after our final determination.

This determination is issued and published in accordance with sections 733(f) and 777(i)(1) of the Act and 19 CFR 351.205(c).

Dated: May 3, 2016.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The merchandise covered by this investigation is circular welded austenitic stainless pressure pipe not greater than 14 inches in outside diameter. References to size are in nominal inches and include all products within tolerances allowed by pipe specifications. This merchandise includes, but is not limited to, the American Society for Testing and Materials ("ASTM") A–312 or ASTM A–778 specifications, or comparable domestic or foreign specifications. ASTM A–358 products are only included when they are produced to meet ASTM A–312 or ASTM A–778 specifications, or comparable domestic or foreign specifications.

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[7] We have preliminarily determined to collapse Sunrise with its affiliate Sun Mark Stainless Pvt, Ltd. (collectively, "Sunrise"). *See* Memorandum to Brendan Quinn, Acting Director, Office III, "Antidumping Duty Investigation on Welded Stainless Pressure Pipe from India: Preliminary Affiliation and Collapsing Memorandum for Sunrise Stainless Private Limited" dated concurrently with this notice.

[8] *See Modification of Regulations Regarding the Practice of Accepting Bonds During the Provisional Measures Period in Antidumping and Countervailing Duty Investigations,* 76 FR 61042 (October 3, 2011).

[9] *See* 19 CFR 351.309.

[10] *See* 19 CFR 351.310(c).

[11] *See* Letter to the Secretary of Commerce from Sunrise "Extension Request for Final Determination" (April 28, 2016).

[12] *See also* 19 CFR 351.210(e).

Excluded from the scope of the investigation are: (1) Welded stainless mechanical tubing, meeting ASTM A–554 or comparable domestic or foreign specifications; (2) boiler, heat exchanger, superheater, refining furnace, feedwater heater, and condenser tubing, meeting ASTM A–249, ASTM A–688 or comparable domestic or foreign specifications; and (3) specialized tubing, meeting ASTM A–269, ASTM A–270 or comparable domestic or foreign specifications.

The subject imports are normally classified in subheadings 7306.40.5005, 7306.40.5040, 7306.40.5062, 7306.40.5064, and 7306.40.5085 of the Harmonized Tariff Schedule of the United States ("HTSUS"). They may also enter under HTSUS subheadings 7306.40.1010, 7306.40.1015, 7306.40.5042, 7306.40.5044, 7306.40.5080, and 7306.40.5090. The HTSUS subheadings are provided for convenience and customs purposes only; the written description of the scope of this investigation is dispositive.

Appendix II

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Period of Investigation
IV. Affiliation and Collapsing
V. Postponement of Final Determination and Extension of Provisional Measures
VI. Scope of the Investigation
VII. Discussion of Methodology
  A. Determination of Comparison Method
  B. Results of the Differential Pricing Analysis
VIII. Date of Sale
IX. Product Comparisons
X. Export Price and Constructed Export Price
XI. Normal Value
  A. Comparison Market Viability
  B. Affiliated-Party Transactions and Arm's-Length Test
  C. Level of Trade
  D. Cost of Production Analysis
  1. Calculation of Cost of Production
  2. Test of Comparison Market Sale Prices
  3. Results of the COP Test
  E. Calculation of NV Based on Comparison Market Prices
XII. Currency Conversion
XIII. Adjustment to Cash Deposit Rates
XIV. U.S. ITC Notification
XV. Disclosure and Public Comment
XVI. Verification
XVII. Conclusion

[FR Doc. 2016–11034 Filed 5–9–16; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–823]

Silicomanganese From India: Preliminary Results of Antidumping Duty Administrative Review; 2014–2015

AGENCY: Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce.

SUMMARY: The Department of Commerce (the Department) is conducting an administrative review of the antidumping duty order on silicomanganese from India pursuant to section 751(a)(1) of the Tariff Act of 1930, as amended (the Act).[1] This review covers one company, Universal Ferro and Allied Chemicals Ltd. (Universal). The period of review (POR) is May 1, 2014, through April 30, 2015. We preliminarily find no evidence of any reviewable entries, shipments, or sales of subject merchandise by Universal during the POR, and are therefore issuing a preliminary no shipments determination.

DATES: *Effective Date:* May 10, 2016.

FOR FURTHER INFORMATION CONTACT: David Lindgren at (202) 482–3870; AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Scope of the Order

The products subject to the order are all forms, sizes and compositions of silicomanganese, except low-carbon silicomanganese, including silicomanganese briquettes, fines and slag. The silicomanganese subject to the order is currently classifiable under subheading 7202.30.0000 of the Harmonized Tariff Schedule of the United States (HTSUS). The HTSUS subheading is provided for convenience and customs purposes. A full description of the scope of the order is contained in the Preliminary Decision Memorandum, which is hereby adopted by this notice.[2] The written description is dispositive.

Methodology

The Department is conducting this review in accordance with section 751(a)(2) of the Tariff Act of 1930, as amended (the Act). For a full description of the methodology underlying our conclusions, see Preliminary Decision Memorandum. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov* and in the Central Records Unit, Room B8024 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly on the Internet at *http://enforcement.trade.gov/frn/index.html.* The signed Preliminary Decision Memorandum is identical in content.

Preliminary Determination of No Shipments

Based on information Universal submitted after the initiation of this administrative review, and due to the fact that we have not received any information from U.S. Customs and Border Protection (CBP) indicating that Universal had entries during the POR, the Department has preliminarily determined that the record evidence indicates that Universal had no reviewable entries during the POR. In addition, the Department finds that it is not appropriate to rescind the review with respect to Universal but, rather, to complete the review and issue appropriate instructions to CBP based on the final results of review, as is our practice.[3]

Assessment Rates

For entries of subject merchandise during the POR produced by Universal which it did not know were destined for the United States, we instructed CBP to liquidate unreviewed entries at the all-others rate if there was no rate for the intermediate company or companies involved in the transaction.[4] We intend to issue assessment instructions directly to CBP 15 days after publication of the final results of this review.

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[1] See *Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 80 FR 37588 (July 1, 2015) (*Initiation*).

[2] For a full description of the scope of the order, *see* Memorandum from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Paul Piquado, Assistant Secretary for Enforcement and Compliance, "Decision Memorandum for the Preliminary Results of the 2014–2015 Administrative Review of the Antidumping Duty Order on Silicomanganese from India (Preliminary Decision Memorandum), dated concurrently with this notice.

[3] *See, e.g., Certain Frozen Warmwater Shrimp From Thailand: Preliminary Results of Antidumping Duty Administrative Review and Intent To Revoke the Order (in Part); 2011–2012,* 78 FR 15686 (March 12, 2013) and the accompanying Decision Memorandum at 7 to 8.

[4] *See Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

Disclosure and Public Comment

Pursuant to 19 CFR 351.309(c), interested parties may submit case briefs no later than 30 days after the date of publication of this notice.[5] Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.[6] Parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[7] Case and rebuttal briefs should be filed using ACCESS.[8] In order to be properly filed, ACCESS must successfully receive an electronically-filed document in its entirety by 5 p.m. Eastern Time on the date on which it is due.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, or to participate if one is requested, must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS, within 30 days after the date of publication of this notice.[9] Requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case briefs.

The Department intends to issue the final results of this administrative review, including the results of its analysis of the issues raised in any written briefs, not later than 120 days after the date of publication of this notice, unless extended, pursuant to section 751(a)(3)(A) of the Act.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

We are issuing and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: May 3, 2016.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2016–11031 Filed 5–9–16; 8:45 am]

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[5] *See* 19 CFR 351.309(c)(ii).

[6] *See* 19 CFR 351.309(d).

[7] *See* 19 CFR 351.309(c)(2) and (d)(2).

[8] *See* 19 CFR 351.303.

[9] *See* 19 CFR 351.310(c).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–122–853]

Citric Acid and Certain Citrate Salts From Canada: Final Results of Antidumping Duty Administrative Review; 2014–2015

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On February 12, 2016, the Department of Commerce (the Department) published the preliminary results of the sixth administrative review of the antidumping duty order on citric acid and certain citrate salts from Canada.[1] The review covers one manufacturer/exporter of the subject merchandise: Jungbunzlauer Canada Inc. (JBL Canada).

No interested party commented on the preliminary results and the Department made no changes to the margin calculation for the final results of this review. Therefore, the final results do not differ from the preliminary results.[2] The final weighted-average dumping margin for JBL Canada is listed below in the "Final Results of Review" section of this notice.

FOR FURTHER INFORMATION CONTACT: Rebecca Trainor or Kate Johnson, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone (202) 482–4007 or (202) 482–4929, respectively.

SUPPLEMENTARY INFORMATION:

Background

The review covers one manufacturer/exporter of the subject merchandise: JBL Canada. On February 12, 2016, the Department published the *Preliminary Results.* We invited parties to comment on the preliminary results of the review. No interested party submitted comments and we made no changes to the margin calculation for the final results of this review. Therefore, the final results are the same as the preliminary results. The Department conducted this administrative review in accordance with section 751 of the Tariff Act of 1930, as amended (the Act).

Scope of the Order

The scope of this order includes all grades and granulation sizes of citric acid, sodium citrate, and potassium citrate in their unblended forms, whether dry or in solution, and regardless of packaging type. The scope also includes blends of citric acid, sodium citrate, and potassium citrate; as well as blends with other ingredients, such as sugar, where the unblended form(s) of citric acid, sodium citrate, and potassium citrate constitute 40 percent or more, by weight, of the blend. The scope of this order also includes all forms of crude calcium citrate, including dicalcium citrate monohydrate, and tricalcium citrate tetrahydrate, which are intermediate products in the production of citric acid, sodium citrate, and potassium citrate. The scope of this order does not include calcium citrate that satisfies the standards set forth in the United States Pharmacopeia and has been mixed with a functional excipient, such as dextrose or starch, where the excipient constitutes at least 2 percent, by weight, of the product. The scope of this order includes the hydrous and anhydrous forms of citric acid, the dihydrate and anhydrous forms of sodium citrate, otherwise known as citric acid sodium salt, and the monohydrate and monopotassium forms of potassium citrate. Sodium citrate also includes both trisodium citrate and monosodium citrate, which are also known as citric acid trisodium salt and citric acid monosodium salt, respectively. Citric acid and sodium citrate are classifiable under 2918.14.0000 and 2918.15.1000 of the Harmonized Tariff Schedule of the United States (HTSUS), respectively. Potassium citrate and crude calcium citrate are classifiable under 2918.15.5000 and 3824.90.9290 of the HTSUS, respectively. Blends that include citric acid, sodium citrate, and potassium citrate are classifiable under 3824.90.9290 of the HTSUS. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise is dispositive.

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[1] *See Citric Acid and Certain Citrate Salts From Canada: Preliminary Results of Antidumping Duty Administrative Review; 2014–2015,* 81 FR 7500 (February 12, 2016) (*Preliminary Results*), and accompanying Decision Memorandum entitled "Decision Memorandum for Preliminary Results of Antidumping Duty Administrative Review: Citric Acid and Certain Citrate Salts from Canada; 2014–2015" (Preliminary Decision Memorandum).

[2] *See* Preliminary Decision Memorandum and Memorandum to The File, "Preliminary Results Margin Calculation for Jungbunzlauer Canada Inc.," dated February 5, 2016.

Period of Review

The period of review is May 1, 2014, through April 30, 2015.

Final Results of Review

As a result of this review, the Department determines that a weighted-average dumping margin of 0.00 percent exists for JBL Canada for the period May 1, 2014, through April 30, 2015.

Assessment Rates

The Department shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries, in accordance with 19 CFR 351.212(b). Pursuant to 19 CFR 356.8(a), the Department intends to issue appropriate appraisement instructions for the respondent subject to this review directly to CBP 41 days after the date of publication of the final results of this review. Because we calculated a zero margin for JBL Canada in the final results of this review, we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for JBL Canada will be zero; (2) for previously reviewed or investigated companies not participating in this review, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a previous review, or the original less-than-fair-value (LTFV) investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 23.21 percent, the all-others rate made effective by the LTFV investigation.[3] These deposit requirements shall remain in effect until further notice.

Notification to Importers

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

This notice serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

This administrative review and notice are published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221.

Dated: May 3, 2016.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2016–11033 Filed 5–9–16; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE534

Taking and Importing of Marine Mammals

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; affirmative finding annual renewal.

SUMMARY: The NMFS Assistant Administrator, (Assistant Administrator) has issued an affirmative finding annual renewal for the Government of El Salvador under the Marine Mammal Protection Act (MMPA). This affirmative finding annual renewal will allow yellowfin tuna and yellowfin tuna products harvested in the eastern tropical Pacific Ocean (ETP) in compliance with the International Dolphin Conservation Program (IDCP) by Salvadoran-flag purse seine vessels or purse seine vessels operating under Salvadoran jurisdiction to be imported into the United States. The affirmative finding annual renewal was based on review of documentary evidence submitted by the Government of El Salvador and obtained from the Inter-American Tropical Tuna Commission (IATTC).

DATES: The affirmative finding annual renewal is effective from April 1, 2015, through March 31, 2016.

FOR FURTHER INFORMATION CONTACT: Justin Greenman, West Coast Region, National Marine Fisheries Service, 501 W. Ocean Blvd., Long Beach, CA 90802. Phone: 562–980–3264. Email: *justin.greenman@noaa.gov.*

SUPPLEMENTARY INFORMATION: The MMPA, 16 U.S.C. 1361 *et seq.*, allows for importation into the United States of yellowfin tuna harvested by purse seine vessels in the ETP under certain conditions. If requested by the harvesting nation, the Assistant Administrator will determine whether to make an affirmative finding based upon documentary evidence provided by the government of the harvesting nation, the IATTC, or the Department of State.

The affirmative finding process requires that the harvesting nation is meeting its obligations under the IDCP and obligations of membership in the IATTC. Every 5 years, the government of the harvesting nation must request a new affirmative finding and submit the required documentary evidence directly to the Assistant Administrator. On an annual basis, NMFS reviews the affirmative finding and determines whether the harvesting nation continues to meet the requirements. A nation may provide information related to compliance with IDCP and IATTC measures directly to NMFS on an annual basis or may authorize the IATTC to release the information to NMFS to annually renew an affirmative finding determination without an application from the harvesting nation.

An affirmative finding will be terminated, in consultation with the Secretary of State, if the Assistant Administrator determines that the requirements of 50 CFR 216.24(f) are no longer being met or that a nation is consistently failing to take enforcement actions on violations, thereby diminishing the effectiveness of the IDCP.

As a part of the affirmative finding process set forth in 50 CFR 216.24(f), the Assistant Administrator considered documentary evidence submitted by the

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[3] *See Citric Acid and Certain Citrate Salts from Canada and the People's Republic of China: Antidumping Duty Orders*, 74 FR 25703 (May 29, 2009).

Government of El Salvador and obtained from the IATTC and has determined that El Salvador has met the MMPA's requirements to receive an affirmative finding annual renewal.

After consultation with the Department of State, the Assistant Administrator issued an affirmative finding annual renewal to El Salvador, allowing the continued importation into the United States of yellowfin tuna and products derived from yellowfin tuna harvested in the ETP by Salvadoran-flag purse seine vessels or purse seine vessels operating under Salvadoran jurisdiction through March 31, 2016. El Salvador's five-year affirmative finding will remain valid through March 31, 2018, subject to subsequent annual reviews by NMFS.

Dated: May 4, 2016.

Eileen Sobeck,

Assistant Administrator for Fisheries, National Marine Fisheries Service.

[FR Doc. 2016–10970 Filed 5–9–16; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE600

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Reef Fish Resources of the Gulf of Mexico; Amendment 42

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of Intent (NOI) to prepare a draft environmental impact statement (DEIS); request for comments.

SUMMARY: The NMFS Southeast Region, in collaboration with the Gulf of Mexico Fishery Management Council (Council), intends to prepare a DEIS to describe and analyze a range of alternatives for management actions to be included in Amendment 42 to the Fishery Management Plan (FMP) for the Reef Fish Resources of the Gulf of Mexico (Amendment 42). Amendment 42 will consider an allocation-based management program for the headboat component of the reef fish recreational fishery in the Gulf of Mexico (Gulf). The purpose of this NOI is to solicit public comments on the scope of issues to be addressed in the DEIS.

DATES: Written comments on the scope of issues to be addressed in the DEIS will be accepted until June 9, 2016.

ADDRESSES: You may submit comments, identified by NOAA–NMFS–2016–0055, by either of the following methods:

- *Electronic submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2016-0055,* click the "Comment Now!" icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit written comments to Susan Gerhart, NMFS Southeast Regional Office, 263 13th Avenue South, St. Petersburg, FL 33701.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter "N/A" in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Susan Gerhart, NMFS Southeast Regional Office, telephone: 727–824–5305; or email: *susan.gerhart@noaa.gov.*

SUPPLEMENTARY INFORMATION: The Council recently took action to provide more flexibility in managing the harvest of red snapper by the various components of the Gulf reef fish recreational sector. In 2014, the Council established separate private angling and Federal charter vessel/headboat (for-hire) components of the red snapper recreational sector. The decrease over time in the proportion of red snapper harvested by anglers fishing from Federal for-hire vessels and differences in regulatory environments faced by Federal for-hire operators and private anglers contributed to the Council's decision to restructure the red snapper recreational sector to increase flexibility for each component. Recreational fishing for other reef fish species has not been as restricted as red snapper, but fishing has closed in Federal waters in recent years for several popular reef fish species with recreational annual catch limits.

In early 2015, the Council requested the development of Amendment 42 to the Fishery Management Plan for Reef Fish Resources of the Gulf of Mexico (Amendment 42) to address management for the headboat component of the Gulf reef fish fishery recreational sector. Management measures under consideration in Amendment 42 include allocation-based programs. The purpose of the proposed measures in Amendment 42 is to reduce management uncertainty and improve economic conditions for operators and owners of Gulf reef fish headboats, and provide flexibility by increasing fishing opportunities for their angler passengers through a management program for Gulf headboats participating in the Southeast Region Headboat Survey (SRHS). The species that may be included in the program developed in Amendment 42 are red snapper, gray triggerfish, greater amberjack, gag, and red grouper.

In the Gulf, one Federal charter vessel/headboat permit for reef fish is issued by NMFS, and the permit does not distinguish between headboats and charter vessels. The SRHS collects catch and effort data from headboats in the Southeast Region, thereby producing a catch history for each vessel included in the survey. In addition, for fishery managers, the SRHS continues to be the sole source for effort and landings estimates for the headboat component as a whole. For these reasons, the vessels included in Amendment 42 are those vessels with Federal charter vessel/headboat permits for reef fish that also have landings in the SRHS, as described in Amendment 42. The availability of vessel-specific landings data through the SRHS may allow development of an allocation-based management program for headboats using those landings histories.

NMFS, in collaboration with the Council, will develop a DEIS for Amendment 42 to describe and analyze alternatives to address the management needs described above, including the "no action" alternative. In accordance with NOAA's Administrative Order 216–6A and the regulations issued by the Council on Environmental Quality (CEQ) for implementing the National Environmental Policy Act (NEPA; 40 CFR parts 1500–1508), NMFS, in collaboration with the Council, has identified preliminary environmental issues as a means to initiate discussion for scoping purposes only. These preliminary issues may not represent the full range of issues that eventually will be evaluated in the DEIS. A copy of the Amendment 42 draft options paper is available at: *http://sero.nmfs.noaa.gov/sustainable_fisheries/gulf_fisheries/reef_fish/index.html.*

Comments on the scope of the DEIS may be submitted in writing to NMFS (see **ADDRESSES**) during the 30-day scoping period. After the scoping period and during the development of

Amendment 42, the Council will accept written comments on the action, and oral comments may be made during the public testimony portion of any Council meeting. The next Council meeting will be June 20–24, 2016, at the Hilton Clearwater Beach, 400 Mandalay Avenue, Clearwater Beach, FL.

After the DEIS associated with Amendment 42 is completed, it will be filed with the Environmental Protection Agency (EPA). After filing, the EPA will publish a notice of availability of the DEIS for public comment in the **Federal Register**. Consistent with the CEQ regulations, the DEIS will have a 45-day public comment period.

The Council and NMFS will consider public comments received on the DEIS in developing the final environmental impact statement (FEIS) and before adopting final management measures for the amendment. NMFS will submit the consolidated final amendment and supporting FEIS to the Secretary of Commerce (Secretary) for review as required by the Magnuson-Stevens Fishery Conservation and Management Act.

NMFS will announce, through a notification in the **Federal Register**, the availability of the final amendment for public review during the Department of Commerce Secretarial review period and will consider all public comments. During Secretarial review, NMFS will also file the FEIS with the EPA, and the EPA will publish a notice of availability for the FEIS in the **Federal Register**. This public comment period is expected to be concurrent with the Secretarial review period and will end prior to final agency action to approve, disapprove, or partially approve Amendment 42.

NMFS will announce, through a document published in the **Federal Register**, all public comment periods on the final amendment, its proposed implementing regulations, and the availability of its associated FEIS. NMFS will consider all public comments received during the Secretarial review period, whether they are on the final amendment, the proposed regulations, or the FEIS, prior to final agency action.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: May 4, 2016.

Emily H. Menashes,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2016–10911 Filed 5–9–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE588

Permanent Advisory Committee to Advise the U.S. Commissioners to the Western and Central Pacific Fisheries Commission; Meeting Announcement

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting

SUMMARY: NMFS announces a public meeting of the Permanent Advisory Committee (PAC) to advise the U.S. Commissioners to the Commission for the Conservation and Management of Highly Migratory Fish Stocks in the Western and Central Pacific Ocean (WCPFC) on June 16, 2016. Meeting topics are provided under the **SUPPLEMENTARY INFORMATION** section of this notice. The meeting will be held via conference call. Members of the public may submit written comments; the comments must be received within 14 days of the completion of the meeting. Mail comments to Emily Crigler at the address provided in the **FOR FURTHER INFORMATION CONTACT** section below.

DATES: The meeting of the PAC will be held via conference call on June 16, 2016, from 10 a.m. to 12 p.m. HST (or until business is concluded).

ADDRESSES: The public meeting will be conducted via conference call. For details on how to call in to the conference line, please contact Emily Crigler, NMFS Pacific Islands Regional Office; telephone: 808–725–5036; email: *emily.crigler@noaa.gov*. Documents to be considered by the PAC will be sent out via email in advance of the conference call. Please submit contact information to Emily Crigler (telephone: 808–725–5036; email: *emily.crigler@noaa.gov*) to receive documents in advance of the call.

FOR FURTHER INFORMATION CONTACT: Emily Crigler, NMFS Pacific Islands Regional Office; 1845 Wasp Blvd., Bldg. 176, Honolulu, HI 96818; telephone: 808–725–5036; facsimile: 808–725–5215; email: *emily.crigler@noaa.gov*.

SUPPLEMENTARY INFORMATION: In accordance with the Western and Central Pacific Fisheries Convention Implementation Act (16 U.S.C. 6901 *et seq.*), the Permanent Advisory Committee, or PAC, has been formed to advise the U.S. Commissioners to the WCPFC. Members of the PAC have been appointed by the Secretary of Commerce in consultation with the U.S. Commissioners to the WCPFC. The PAC supports the work of the U.S. National Section to the WCPFC in an advisory capacity. The U.S. National Section is made up of the U.S. Commissioners and the Department of State. NMFS Pacific Islands Regional Office provides administrative and technical support to the PAC in cooperation with the Department of State. More information on the WCPFC, established under the Convention on the Conservation and Management of Highly Migratory Fish Stocks in the Western and Central Pacific Ocean, can be found on the WCPFC Web site: *http://wcpfc.int/*.

Meeting Topics

The purpose of the June 16, 2016, conference call is to discuss outcomes of the 2015 regular annual session of the WCPFC (WCPFC12) and to begin soliciting recommendations leading up to the 2016 regular annual session of the WCPFC. The next regular annual session of the WCPFC (WCPFC13) is scheduled to be held December 5—December 9, 2016, in Fiji.

Special Accommodations

The conference call is accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Emily Crigler at 808–725–5036 at least ten working days prior to the meeting.

Authority: 16 U.S.C. 6902

Dated: May 4, 2016.

Emily H. Menashes,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2016–10912 Filed 5–9–16; 8:45 am]

BILLING CODE 3510–22–P

COMMODITY FUTURES TRADING COMMISSION

Agency Information Collection Activities Under OMB Review

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice.

SUMMARY: The Office of Customer Education and Outreach (OCEO), Commodity Futures Trading Commission (“CFTC” or “Commission”), invites public comment on its proposed Information Collection Request (ICR), in compliance with the Paperwork Reduction Act (PRA), for the Generic Clearance for the Qualitative Collection of Feedback for Agency Service Delivery. The ICR abstracted below, has been submitted to the Office

of Management and Budget (OMB) for approval. The ICR describes the nature of the information collection and its expected costs and burden.

DATES: Comments must be submitted on or before June 9, 2016.

FOR FURTHER INFORMATION CONTACT: Nisha Smalls, Office of Customer Education and Outreach, Commodity Futures Trading Commission, 1155 21st Street NW., Washington, DC 20581, (202) 418–5895; FAX: (202) 418–5541; email: *nsmalls@cftc.gov* and refer to this **Federal Register** notice.

ADDRESSES: Comments regarding the burden estimated or any other aspect of the information collection, including suggestions for reducing the burden, may be submitted directly to the Office of Information and Regulatory Affairs (OIRA) in OMB, within 30 days of the notice's publication, by email at *OIRAsubmissions@omb.eop.gov.* Please identify the comments by OMB Control No. 3038–0107. Please provide the Commission with a copy of all submitted comments at the address listed below. Please refer to OMB Reference No. 3038–0107, found on *http://reginfo.gov.* Comments may also be mailed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for the Commodity Futures Trading Commission, 725 17th Street NW., Washington, DC 20503, or submitted through the Agency's Web site at *http://comments.cftc.gov.* Follow the instructions for submitting comments through the Web site.

Comments may also be mailed to: Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581 or by Hand Delivery/Courier at the same address.

A copy of the supporting statements for the collection of information discussed above may be obtained by visiting *reginfo.gov.* All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to *http://www.cftc.gov.*

SUPPLEMENTARY INFORMATION

Title: Generic Clearance for the Qualitative Collection of Feedback for Agency Service Delivery.

Abstract: The information collection activity will consist of a variety of activities over the next few years including customer outreach and information-sharing with stakeholders that are responsive to customers' needs and sensitive to changes in the customer market. The proposed information collection activities will use similar methods for information collection or otherwise share common elements, and provide a means to gather customer and stakeholder feedback in an efficient, timely manner. By feedback we mean information that provides useful information on perceptions and opinions. The solicitation of information will address such areas as appropriate messages, effective message delivery methods, effective programming, programming needs, and customer beliefs, psychographics and social norms that will assist the agency in developing outreach and communications plans. Since these systems will use similar methods for information collection or otherwise share common elements, the OCEO is proposing a generic clearance for this process which will allow the OCEO to implement these systems and meet the obligations of the PRA without the delays of the normal clearance process. The **Federal Register** notice with a 60-day comment period soliciting comments on this collection of information was published on March 4, 2016 (81 FR 11520).

Burden statement: The preliminary estimate of aggregate burden for this generic clearance follows. The estimate of the number of respondents is a projection and could change significantly based on the collection method ultimately used in the research.

Respondents/Affected Entities: 1,440.

Estimated number of responses: 10 per year.

Estimated total annual burden on respondents: 14,400 responses.

Frequency of collection: Once per request.

Average minutes per response: 120.

Estimated total annual burden hours requested: 28,800 hours.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: May 4, 2016.

Robert N. Sidman,

Deputy Secretary of the Commission.

[FR Doc. 2016–10847 Filed 5–9–16; 8:45 am]

BILLING CODE 6351–01–P

COMMODITY FUTURES TRADING COMMISSION

Agency Information Collection Activities Under OMB Review

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (PRA), this notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to the Office of Management and Budget (OMB) for review and comment. The ICR describes the nature of the information collection and its expected costs and burden.

DATES: Comments must be submitted on or before June 9, 2016.

ADDRESSES: Comments regarding the burden estimated or any other aspect of the information collection, including suggestions for reducing the burden, may be submitted directly to the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB), within 30 days of the notice's publication by email at *OIRAsubmissions@omb.eop.gov.* Please identify the comments by "OMB Control No. 3038–0104 (Exemption for Swaps Between Affiliates)." Please provide the Commodity Futures Trading Commission ("CFTC" or "Commission") with a copy of all submitted comments at the address listed below. Please refer to OMB Reference Nos. 3038–0104, found on *http://reginfo.gov.* Comments may also be mailed to OIRA, OMB, Attention: Desk Officer for the Commodity Futures Trading Commission, 725 17th Street NW., Washington, DC 20503, and to the Commission through its Web site at *http://comments.cftc.gov.* Follow the instructions for submitting comments through the Web site.

Comments may also be mailed to: Christopher Kirkpatrick, Secretary, Commodity Futures Trading Commission, 1155 21st Street NW., Washington, DC 20581 or by Hand Delivery/Courier at the same address.

A copy of the supporting statements for the collection of information discussed above may be obtained by visiting *http://regInfo.gov.* All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to *http://www.cftc.gov.* You should submit only information that you wish to make available publicly. If you wish the Commission to consider information that is exempt from disclosure under the Freedom of Information Act, a petition for confidential treatment of the exempt information may be submitted according to the procedures set forth in section 145.9 of the Commission's regulations.

FOR FURTHER INFORMATION CONTACT: Peter Kals, Division of Clearing and Risk, Commodity Futures Trading Commission, (202) 418–5466; email: *pkals@cftc.gov,* and refer to OMB Control No. 3038–0104.

SUPPLEMENTARY INFORMATION:

Title: Exemption for Swaps Between Affiliates (OMB Control No. 3038–

0104). This is a request for extension of a currently approved information collection.

Abstract: Section 2(h)(1)(A) of the Commodity Exchange Act requires certain entities to submit for clearing certain swaps if they are required to be cleared by the Commission. Rule 50.52 permits certain affiliated entities to elect not to clear certain inter-affiliate swaps that otherwise would be required to be cleared, provided that they meet certain conditions. The rule further requires the reporting of certain information if the exemption is elected. This collection pertains to information the Commission needs to monitor use of the exemption and assess market risk in connection therewith. The collections of information are required to obtain the exemption. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The Commission did not receive any comments on the 60-day **Federal Register** notice, 81 FR 11762, dated March 7, 2016.

Burden Statement: The respondent burden for this collection is estimated to require one hour per response.

Respondents/Affected Entities: Swap dealers and other multinational corporations.

Estimated Number of Respondents: 75.

Estimated Average Burden Hours per Respondent: 1 hour.

Estimated Total Average Annual Burden Hours on Respondents: 75 hours.

Frequency of Collection: Annually; on occasion.

There are no capital costs or operating and maintenance costs associated with this collection.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: May 4, 2016.

Robert N. Sidman,

Deputy Secretary of the Commission.

[FR Doc. 2016–10848 Filed 5–9–16; 8:45 am]

BILLING CODE 6351–01–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Information Collection; Submission for OMB Review, Comment Request

AGENCY: Corporation for National and Community Service.

ACTION: Notice.

SUMMARY: The Corporation for National and Community Service (CNCS) has submitted a public information collection request (ICR) entitled President's Volunteer Service Awards, part A, B, C, D, E and F for review and approval in accordance with the Paperwork Reduction Act of 1995, Public Law 104–13, (44 U.S.C. Chapter 35). Copies of this ICR, with applicable supporting documentation, may be obtained by calling the Corporation for National and Community Service, David Premo, at 202–606–6717 or email to *dpremo@cns.gov*. Individuals who use a telecommunications device for the deaf (TTY–TDD) may call 1–800–833–3722 between 8:00 a.m. and 8:00 p.m. Eastern Time, Monday through Friday.

DATES: Comments may be submitted, identified by the title of the information collection activity, within June 9, 2016.

ADDRESSES: Comments may be submitted, identified by the title of the information collection activity, to the Office of Information and Regulatory Affairs, Attn: Ms. Sharon Mar, OMB Desk Officer for the Corporation for National and Community Service, by any of the following two methods within 30 days from the date of publication in the **Federal Register**:

(1) By fax to: 202–395–6974, Attention: Ms. Sharon Mar, OMB Desk Officer for the Corporation for National and Community Service; or

(2) By email to: *smar@omb.eop.gov*.

SUPPLEMENTARY INFORMATION: The OMB is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of CNCS, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Propose ways to enhance the quality, utility, and clarity of the information to be collected; and
- Propose ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments

A 60-day Notice requesting public comment was published in the **Federal Register** on Wednesday, February 17, 2016, at Volume 81, Number 31 FR 8054. This comment period ended April 18, 2016. No public comments were received from this Notice.

Description: CNCS is seeking the renewal of the President's Volunteer Service Awards (PVSA), parts A, B, C, D, E and F. This information will be provided by certifying organizations which will include non-profits, schools, universities, businesses and faith based organizations. This is a voluntary submission in order to place an order for an award.

Type of Review: Renewal.

Agency: Corporation for National and Community Service.

Title: President's Volunteer Service Awards, parts A, B, C, D, E and F.

OMB Number: 3045–0086.

Agency Number: None.

Affected Public: General public.

Total Respondents: 200,000.

Frequency: On occasion.

Average Time per Response: Averages 20 minutes.

Estimated Total Burden Hours: 66,666 hours.

Total Burden Cost (capital/startup): None.

Total Burden Cost (operating/maintenance): None.

Dated: May 4, 2016.

Theodore Miller,

Chief of External Affairs.

[FR Doc. 2016–10859 Filed 5–9–16; 8:45 am]

BILLING CODE 6050–28–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 16–28]

36(b)(1) Arms Sales Notification

AGENCY: Department of Defense, Defense Security Cooperation Agency.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996.

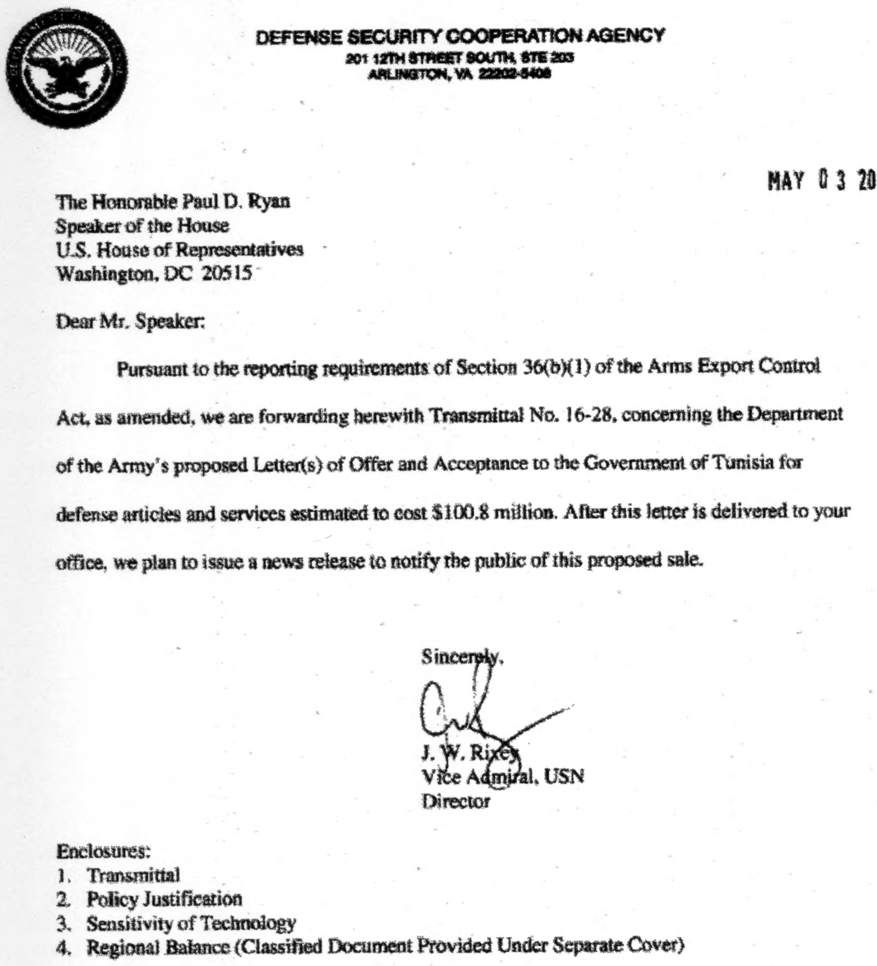
FOR FURTHER INFORMATION CONTACT: Heather N. Harwell, DSCA/LMO, (703) 697–9217.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 16–28 with attached Policy Justification and Sensitivity of Technology.

Dated: May 4, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.



DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

MAY 03 2016

The Honorable Paul D. Ryan
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 16-28, concerning the Department of the Army's proposed Letter(s) of Offer and Acceptance to the Government of Tunisia for defense articles and services estimated to cost $100.8 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

J. W. Rixey
Vice Admiral, USN
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology
4. Regional Balance (Classified Document Provided Under Separate Cover)

Transmittal No. 16–28

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Government of Tunisia

(ii) *Total Estimated Value:*

Major Defense Equipment*	$44.3 million
Other	$56.5 million
TOTAL	$100.8 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:*

Major Defense Equipment (MDE):

Twenty-five (25) Embedded GPS/Inertial (EGI) Navigation Systems (INS)
Twenty-four (24) AN/AAR–57 Common Missile Warning Systems (CMWS)
Ten (10) AGM–114R Hellfire Missiles
Eighty-two (82) Advanced Precision Kill Weapon System (APKWS) Rounds

Non-MDE:

This request includes the following Non-MDE:

To be installed on each of the twenty-four (24) EDA OH–58D aircraft: one (1) SHP Rolls-Royce 250–C30R/3 Engine, one (1) AN/ARC–164 UHF Radio, one (1) AN/ARC–186 VHF Radio, one (1) PC–DTS–V Data Recorder, two (2) AN/ARC–201D Radios, one (1) AN/APX–118 IFF Transponder, one (1) AN/APR–39A(V)1/4 Radar Signal Detecting Set, one (1) AN/AVR–2B Laser Warning Receiver, one (1) M134 DH Mini-Gun, one (1) M3P Aircraft Gun System, and two (2) M260 Rocket Launchers.

This request also includes: fifty (50) AN/AVS–6 Night Vision Goggles (NVGs), five-hundred thousand (500,000) 12.7mm rounds for the M3P Gun System, 2.3 million 7.62mm rounds for the M134DH Mini-Gun, the A965M1 Decoy Chaff Cartridges, M211 and M212 Advance Infrared Countermeasures Munition flares, eighty-two (82) MK66 MOD 4 2.75 rocket motors and eighty-two (82) M152 High Explosive (HE) warheads to support the APKWS, one (1) EGI for the Combined Armament Avionics Electrical Trainers, six (6) M279A1 Hellfire Launchers, associated test and support equipment, technical support, the Army's Non-Standard Rotary Wing Aviation Program Manager's Office (NSRWA PMO) technical support, Security Assistance Management Directorate's (SAMD) program technical support, additional contractor support, Peculiar Ground Support Equipment (PGSE), Post Production Support Services (PPSS), Government Furnished Equipment (GFE), Retrofit Service Notice (RSN), Repair and Return (R&R), communication and navigation equipment, aircraft survivability equipment, displays, flyable storage, transportation of aircraft, publications, and training.

(iv) *Military Department:* Army (IBD)

(v) *Prior Related Cases, if any:* TU–B–USS–12 JAN 15-$405M

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* See Annex attached.

(viii) *Date Report Delivered to Congress:* 03 May 2016

* as defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Tunisia—OH–58D Kiowa Warrior Aircraft Equipment and Support:

The Government of Tunisia has requested a possible sale of:

Major Defense Equipment (MDE):

Twenty-five (25) Embedded GPS/Inertial (EGI) Navigation Systems (INS)
Twenty-four (24) AN/AAR–57 Common Missile Warning Systems (CMWS)
Ten (10) AGM–114R Hellfire Missiles
Eighty-two (82) Advanced Precision Kill Weapon System (APKWS) Rounds

This request includes the following Non-MDE:

To be installed on each of the twenty-four (24) EDA OH–58D aircraft: one (1) SHP Rolls-Royce 250–C30R/3 Engine, one (1) AN/ARC–164 UHF Radio, one (1) AN/ARC–186 VHF Radio, one (1) PC–DTS–V Data Recorder, two (2) AN/ARC–201D Radios, one (1) AN/APX–118 IFF Transponder, one (1) AN/APR–39A(V)1/4 Radar Signal Detecting Set, one (1) AN/AVR–2B Laser Warning Receiver, one (1) M134 DH Mini-Gun, one (1) M3P Aircraft Gun System, and two (2) M260 Rocket Launchers.

This request also includes: fifty (50) AN/AVS–6 Night Vision Goggles (NVGs), five-hundred thousand (500,000) 12.7mm rounds for the M3P Gun System, 2.3 million 7.62mm rounds for the M134DH Mini-Gun, the A965M1 Decoy Chaff Cartridges, M211 and M212 Advance Infrared Countermeasures Munition flares, eighty-two (82) MK66 MOD 4 2.75 rocket motors and eighty-two (82) M152 High Explosive (HE) warheads to support the APKWS, one (1) EGI for the Combined Armament Avionics Electrical Trainers, six (6) M279A1 Hellfire Launchers, associated test and support equipment, technical support, the Army's Non-Standard Rotary Wing Aviation Program Manager's Office (NSRWA PMO) technical support, Security Assistance Management Directorate's (SAMD) program technical support, additional contractor support, Peculiar Ground Support Equipment (PGSE), Post Production Support Services (PPSS), Government Furnished Equipment (GFE), Retrofit Service Notice (RSN), Repair and Return (R&R), communication and navigation equipment, aircraft survivability equipment, displays, flyable storage, transportation of aircraft, publications, and training.

The total estimated value of MDE is $44.3 million. The total overall estimated value is $100.8 million.

Tunisia has been approved to receive twenty-four (24) OH–58D Kiowa Warrior Helicopters via the Excess Defense Articles (EDA) Program under a separate notification. That separate notification included only the OH–58D airframes, thus this transmittal includes all the major components and customer-unique requirements requested to supplement the EDA grant transfer.

This proposed sale will contribute to the foreign policy and national security objectives of the United States by helping to improve the security of Tunisia which has been, and continues to be an important force for political stability and economic progress in the North African region. The United States is committed to the security of Tunisia, and it is vital to U.S. national interests to assist Tunisia to develop and maintain a strong and ready self-defense capability.

The OH–58D Kiowa Warrior helicopters along with the parts, systems, and support enumerated in this notification will improve Tunisia's capability to conduct border security and combat operations against terrorists, including Al-Qaida in the Islamic Maghreb (AQIM), Islamic State in Iraq and the Levant (ISIL) in Libya, and Ansar al-Sharia, Tunisia (AAS–T). These helicopters will further modernize the Tunisian armed forces and increase its interoperability with U.S. forces and other coalition partners. Tunisia will have no difficulty absorbing this equipment into its armed forces.

The proposed sale will not alter the basic military balance in the region.

The principal contractor for this effort is unknown and will be determined during contract negotiations. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will require the assignment of approximately ten (10) additional U.S. Government and approximately fifteen (15) contractor representatives to Tunisia for approximately five (5) years to support the fielding, maintenance, and personal training.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 16–28

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex

Item No. vii

(vii) *Sensitivity of Technology:*

1. This sale will involve the release of sensitive technology to Tunisia. The OH–58D Kiowa Warrior Helicopter weapons system is classified up to SECRET. The OH–58D aircraft features advanced avionics and other technologically sensitive systems. Aircraft in the U.S. Government configuration will be equipped with one (1) SHP Rolls-Royce 250–C30R/3 Engine, one (1) AN/ARC–164 UHF Radio, one (1) AN/ARC–186 VHF Radio, one (1) PC–DTS–V Data Recorder, two (2) AN/ARC–201D Radios, one (1) AN/APX–118 IFF Transponder, one (1) Embedded GPS/Inertial (EGI) Navigation System (INS), one (1) AN/APR–39A(V)1/4 Radar Signal Detecting Set, one (1) AN/AAR–57 Common Missile Warning System (CMWS), one (1) AN/AVR–2B Laser Warning Receiver, one (1) M134 DH Mini-Gun, one (1) M3P Aircraft Gun System, two (2) M260 Rocket Launchers, Hellfire Missile System, the Advanced Precision

Kill Weapon System (APKWS), AN/AVS–6 Night Vision Goggles (NVGs), the AGM–114R Hellfire Missile, A965M1 Decoy Chaff Cartridges, M211 and M212 Advance Infrared Countermeasures Munition flares.

2. Sensitive and/or classified (up to SECRET) elements of the proposed OH–58D Kiowa Warrior Helicopter sale include hardware, accessories, components, and associated software: Embedded GPS/Inertial (EGI) Navigation System (INS), the AN/AAR–57 Common Missile Warning System (CMWS), the AN/APX–118 Transponder Identify Friend or Foe (IFF), the AN/APR–39A(V)1/4 Radar Signal Detecting Set, the AN/AVR–2B Laser Detecting Set, the AN/AVS–6 Night Vision Goggles (NVGs), the AGM–114R Hellfire Missiles, the Advanced Precision Kill Weapon System (APKWS) All-Up-Rounds (AURs), A965M1 Decoy Chaff Cartridge, and the M211 and M212 Advance Infrared Countermeasures Munition flares. Additional sensitive information includes operating manuals, and maintenance technical orders containing performance information, operating and test procedures, and other information related to support operations and repair. The hardware, software, and data identified are classified to protect vulnerabilities, design, and performance parameters, and other similar critical information.

a. The EGI/INS is a navigation platform that combines an inertial sensor assembly with a fixed reception pattern antenna GPS receiver and a common Kalman filter. The EGI system is the primary source for position information. The EGI is UNCLASSIFIED. The GPS crypto variable keys needed for highest GPS accuracy are classified up to SECRET.

b. The AN/AAR–57 Common Missile Warning System utilizes electro-optical sensors to warn the aircrew of threatening missile launch and approach. This system detects and performs data hand-off so countermeasures can be automatically dispensed. The system provides pilots hostile fire indication. The system hardware components are UNCLASSIFIED without installed software. When software is installed, the system is classified up to CONFIDENTIAL.

c. The AN/APX–118 Identification Friend or Foe combined transponder interrogator system is UNCLASSIFIED unless evaluator parameters are enabled, which are SECRET.

d. The AN/APR–39A(V)1/4 Radar Signal Detecting Set provides warning of radar directed threats to allow appropriate evasive maneuvers and deployment of radar countermeasures. The system hardware components are UNCLASSIFIED without installed software. When the software is installed, the system is classified up to CONFIDENTIAL.

e. The AN/AVR–2B Laser Detecting Set is a passive laser warning system that can receive, process, and provide for the display of threat information. The system, hardware components, and software are UNCLASSIFIED.

f. The AN/AVS–6 Night Vision Goggles (NVG) is a 3rd generation aviation NVG offering higher resolution, high gain, and photo response to near infrared. Hardware is UNCLASSIFIED, and technical data and documentation to be provided are UNCLASSIFIED.

g. The AGM–114R Hellfire Missile has sensitive technology contained within operational semi-active laser seeker. The highest level for release of the AGM–114R is SECRET, based upon the semi-active seeker and warhead. Reverse engineering could reveal CONFIDENTIAL information. Vulnerability data, countermeasures, vulnerability/susceptibility analyses, and threat definitions are classified SECRET or CONFIDENTIAL.

h. The Advanced Precision Kill Weapon System (APKWS) All-Up-Round (AUR) is an air-to-ground weapon that consists of an APKWS Guidance Section (GS), 2.75-inch MK66 Mod 4 rocket motor, and MK152 warhead/fuze. APKWS uses a semi-active laser seeker. The GS is installed between the rocket motor and warhead to create a guided rocket. The APKWS may be procured as an independent component to be mated to appropriate 2.75-inch warheads/fuzes and rocket motors purchased separately or may be purchased as an AUR. The overall classification is SECRET.

i. The A965M1 is a 25.4mm Decoy Chaff Cartridge. All cartridge components including the cartridge case, piston, end cap, and theoretical band coverage are UNCLASSIFIED. The specifications and drawings for this item are also UNCLASSIFIED. Radar Cross Section (RCS) measurements of deployed chaff are CONFIDENTIAL. Chaff deployment timing, sequence, pattern, and effectiveness against radar threats are SECRET/NOFORN.

3. Software, hardware, and other data/information, which is classified or sensitive, is reviewed prior to release to protect system vulnerabilities, design data, and performance parameters. Some end-item hardware, software, and other data identified above are classified at the CONFIDENTIAL and SECRET level. Potential compromise of these systems is controlled through management of the basic software programs of highly sensitive systems and software-controlled weapon system on a case-by-case basis.

4. If a technologically advanced adversary were to obtain knowledge of the specific hardware and software elements, the information could be used to develop countermeasures that might reduce weapon system effectiveness or be used in the development of a system with similar capabilities. Weapon system effectiveness to persecute adversaries kinetically and strategically would be greatly compromised, and interoperability with friendly forces would be adversely impacted.

5. A determination has been made that Tunisia, the recipient country, can provide the same degree of protection for the sensitive technology being released as the U.S. Government. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the Policy Justification.

6. All defense articles and services listed in this transmittal have been authorized for release and export to the Government of Tunisia.

[FR Doc. 2016–10910 Filed 5–9–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 16–22]

36(b)(1) Arms Sales Notification

AGENCY: Department of Defense, Defense Security Cooperation Agency.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996.

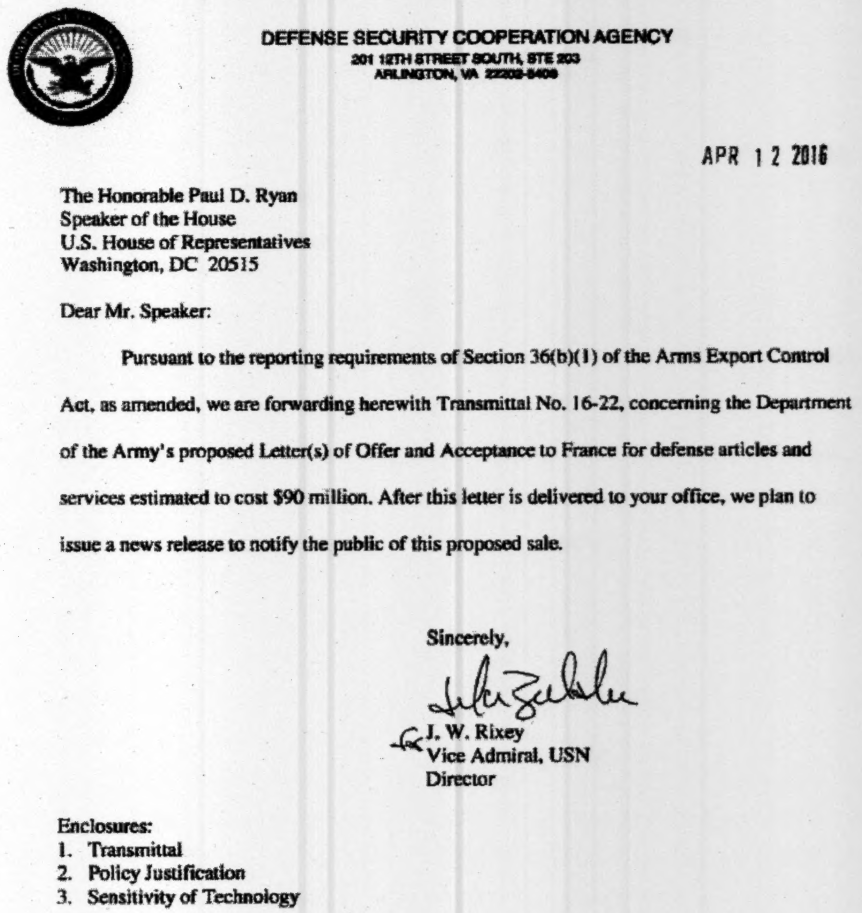
FOR FURTHER INFORMATION CONTACT: Heather N. Harwell, DSCA/LMO, (703) 697–9217.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 16–22 with attached Policy Justification.

Dated: May 4, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.



DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

APR 12 2016

The Honorable Paul D. Ryan
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 16-22, concerning the Department of the Army's proposed Letter(s) of Offer and Acceptance to France for defense articles and services estimated to cost $90 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

J. W. Rixey
Vice Admiral, USN
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology

Transmittal No. 16–22

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Government of France

(ii) *Total Estimated Value:*

Major Defense Equipment*	$60 million
Other	$30 million
TOTAL	$90 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:*

Major Defense Equipment (MDE): Twenty-one (21) Guided Multiple Launch Rocket System (GMLRS) Unitary Rocket Pods (six (6) rockets per pod for a total of one-hundred and twenty-six (126))

Non-MDE: Also included are a GMLRS Unitary Quality Assurance Team (QAT), GMLRS publications, live fire data, software updates, and technical assistance.

(iv) *Military Department:* U.S. Army (WAN)

(v) *Prior Related Cases, if any:* None

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* See Attached Annex.

(viii) *Date Report Delivered to Congress:* 12 April 2016

* as defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

France—Guided Multiple Launch Rocket System (GMLRS) Unitary Rocket Pods and Related Support

The Government of France has requested a possible sale of twenty-one (21) GMLRS Unitary Rocket Pods. Also included are a GMLRS Quality Assurance Team (QAT), GMLRS publications, live fire data, software updates, and technical assistance. The total estimated value of MDE is $60 million. The overall total estimated value is $90 million.

This proposed sale will enhance the foreign policy and national security objectives of the United States by helping to improve the security of a NATO ally which has been, and continues to be an important force for political stability and economic progress. It is vital to the U.S. national interest to assist France to develop and maintain a strong and ready self-defense capability.

France intends to use these missiles to expand its existing army architecture and improve its self-defense capabilities. France is a co-developer of the GMLRS and has operational requirements for additional missiles. France will have no difficulty absorbing this equipment into its armed forces.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The U.S. Army procured the GMLRS Unitary from Lockheed Martin Industries, Camden, Arkansas. The sale of these GMLRS Unitary will be from U.S. stock; therefore, Lockheed Martin will not be involved. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will require U.S. Government and contractor representatives to travel to France for equipment de-processing, fielding, system checkout, and new equipment training.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 16–22

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

Annex

Item No. vii

(vii) *Sensitivity of Technology:*

1. The Guided Multiple Launch Rocket System (GMLRS) M31 Unitary is the Army's primary munition for units fielding the High Mobility Artillery Rocket Systems (HIMARS) and Multiple Launcher Rocket Systems (MLRS) M270A1 Rocket and Missile Launcher platforms. The M31 Unitary is a solid propellant artillery rocket that uses Global Positioning System (GPS)-aided inertial guidance to accurately and quickly deliver a single high-explosive blast fragmentation warhead on to point targets at ranges from 15 to 70 kilometers. The rockets are fired from a launch pod container that also serves as the storage and transportation container for the rockets. Each rocket pod holds six (6) total rockets.

2. The GMLRS Unitary employs a multi-mode fuze consisting of an Electronic Safe and Arm Fuze (ESAF) and a Frequency-Modulating Continuous Wave-Directional Doppler Ranging (FMCW–DDR) height-of-burst sensor. The weapon has three fuzing modes—point detonating, post-impact time delay, and proximity height of burst—which are all accomplished automatically via a launcher/fire control system electrical interface prior to launch. The height-of-burst sensor is not integrated with the fuze, but provides fire pulse input and interfaces with a mechanical fuze.

3. The Army's FMCW–DDR height-of-burst technology comprises components and software requiring special production skills and is deemed state of the art. The sensitive aspects of the technology reside primarily in the design, development, production, and manufacturing data for the related components (integrated circuits and flex cable assembly) and in the methodology required to integrate those components onto the flex cable assembly to process embedded data (the software, algorithm, and operating parameters). The sole technology aspect of the FMCW–DDR present in the M31 proximity height-of-burst sensor is the signal processing algorithm (*i.e.* processing techniques) modified specifically for use in the M31. The disclosure of know-how, software, and other associated documentation for this sensitive technology is not authorized under this sale.

4. A determination has been made that Government of France can provide the same degree of protection for the sensitive technology being released as the U.S. Government. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the Policy Justification.

5. All defense articles and services listed in this transmittal have been authorized for release and export to the Government of France.

[FR Doc. 2016–10890 Filed 5–9–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

Application for New Awards; Charter Schools Program (CSP)—Grants for Replication and Expansion of High-Quality Charter Schools

AGENCY: Office of Innovation and Improvement, Department of Education.

ACTION: Notice.

SUMMARY: Overview Information: CSP—Grants for Replication and Expansion of High-Quality Charter Schools Notice inviting applications for new awards for fiscal year (FY) 2016.

Catalog of Federal Domestic Assistance (CFDA) Number: 84.282M.

DATES: Applications Available: May 10, 2016.

Date of Pre-Application Webinar: June 16, 2016, 2:00 p.m. to 3:30 p.m., Washington, DC, time.

Deadline for Transmittal of Applications: June 20, 2016.

Deadline for Intergovernmental Review: August 23, 2016.

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purpose of the CSP is to increase national understanding of the charter school model by expanding the number of high-quality charter schools (as defined in this notice) available to students across the Nation; providing financial assistance for the planning, program design, and initial implementation of charter schools; and evaluating the effects of charter schools, including their effects on students, student academic achievement, staff, and parents.

The purpose of the CSP Grants for Replication and Expansion of High-Quality Charter Schools (Replication and Expansion) competition (CFDA 84.282M) is to award grants to eligible applicants to enable them to replicate (as defined in this notice) or expand high-quality charter schools (as defined in this notice) with demonstrated records of success, including success in increasing student academic achievement. Eligible applicants may use their grant funds to expand the enrollment of one or more existing charter schools by substantially increasing the number of available seats per school, or to open one or more new charter schools that are based on the charter school model for which the eligible applicant has presented evidence of success.

SUPPLEMENTARY INFORMATION: On December 10, 2015, the President signed into law the Every Student Succeeds

Act (ESSA), Public Law 114–95, which reauthorized the Elementary and Secondary Education Act of 1965 (ESEA), as amended by the No Child Left Behind Act of 2001 (NCLB). Under section 5(c) of ESSA, CSP grants awarded in FY 2016 and earlier years will operate in accordance with the requirements of the ESEA, as amended by NCLB, and any continuation awards applicable to these grants also will operate in accordance with such requirements.

For this year's competition, the Department uses the same absolute priorities, competitive preference priorities, and selection criteria as in FY 2015, because we believe these facilitated a large number of high-quality applications and a diverse pool of applicants. In developing their applications, applicants should review the application package available at *www.Grants.gov* for additional information concerning the priorities, application requirements, and selection criteria of this notice, as well as more detailed information on the submission process.

Like the FY 2015 Replication and Expansion grant competition, this notice includes two absolute priorities for applicants with Experience Operating or Managing High-Quality Charter Schools, and for applicants serving a Low-Income Demographic. The first absolute priority requires applicants to operate or manage more than one high-quality charter school (as defined in this notice), and the second requires applicants to demonstrate that at least 60 percent of the students in the charter schools it operates or manages are from low-income families. Applicants should review the application package for additional information concerning the absolute priorities. Both absolute priorities are from the final priorities, requirements, and selection criteria for this program, published in the **Federal Register** on July 12, 2011 (76 FR 40898) (Final Priorities), and are intended to ensure that projects are designed to meet the needs of educationally disadvantaged and other students.

The FY 2016 Replication and Expansion grant competition also includes the same three competitive preference priorities as the FY 2015 Replication and Expansion competition. Applicants addressing Competitive Preference Priority 1 may select and address only one of three parts of the priority. Part (a) of Competitive Preference Priority 1 is for projects designed to support students who are members of federally recognized Indian tribes and is from the Secretary's final supplemental priorities and definitions for discretionary grant programs, published in the **Federal Register** on December 10, 2014 (79 FR 73425) (Supplemental Priorities). Part (b) of Competitive Preference Priority 1 is for projects designed to replicate (as defined in this notice) and expand high-quality charter schools in order to support school improvement efforts by local educational agencies (LEAs) and is from the Final Priorities for this program. Part (c) of Competitive Preference Priority 1 is for projects designed to replicate (as defined in this notice) and expand high-quality charter schools (as defined in this notice) in federally designated Promise Zones, and is from the notice of final priority for Promise Zones, published in the **Federal Register** on March 27, 2014 (79 FR 17035) (Promise Zones Priority). The thirteen Promise Zones that have been designated thus far are located in Camden City, New Jersey; the Chocktaw Nation of Oklahoma; East Indianapolis, Indiana; Los Angeles, California; the Lowlands of South Carolina; Minneapolis, Minnesota; North Hartford, Connecticut; Philadelphia, Pennsylvania; Pine Ridge, South Dakota; Sacramento, California; San Antonio, Texas; Southeastern Kentucky; and St. Louis, Missouri. Another Promise Zones competition is currently underway and new designees are expected to be announced in the spring of 2016. If new designees are announced prior to the deadline for transmittal of applications for this competition, applicants may meet this priority by submitting the requisite HUD form 50153, signed by an authorized representative of the lead organization of the newly designated Promise Zone.

The second competitive preference priority is *Promoting Diversity.* It is from the Final Priorities for this program. This priority awards additional points to applications that demonstrate a record of, and an intent to continue, taking active measures to promote diversity by bringing together students of different backgrounds, such as different racial, ethnic, and socioeconomic backgrounds, and to serve students with disabilities and English learners at rates comparable to the rates at which these students are served in public schools in the surrounding area. In connection with developing responses to this priority, applicants are encouraged to refer to the joint guidance issued by the Department's Office for Civil Rights and the U.S. Department of Justice entitled, "Guidance on the Voluntary Use of Race to Achieve Diversity and Avoid Racial Isolation in Elementary and Secondary Schools" (*www2.ed.gov/about/offices/list/ocr/docs/guidance-ese-201111.pdf*) and "Schools' Civil Rights Obligations to English Learner Students and Limited English Proficient Parents" (*www2.ed.gov/about/offices/list/ocr/ellresources.html*).

The third competitive preference priority is Novice Applicants (as defined in this notice). It is from 34 CFR 75.225(c)(2). This priority provides additional points to applicants that have neither received a CSP Replication and Expansion grant—either individually or as part of a group—at any point in the past nor received a discretionary grant from the Federal government in the previous five years.

The FY 2016 Replication and Expansion grant competition also continues to include an invitational priority that encourages applicants to conduct rigorous evaluations of practices within their schools that will, if well implemented, produce evidence that meets What Works Clearinghouse (WWC) Evidence Standards (as defined in this notice). The Department remains committed to building evidence of the effectiveness of a range of educational practices, increasing the number of schools that implement practices that are based on evidence, and identifying and evaluating practices that other schools or school systems could adopt to improve outcomes for their students (*e.g.,* educator induction practices or school discipline policies).

Finally, the Consolidated Appropriations Act, 2016, Division H, Pub. L. 114–113 (FY 2016 Appropriations Act), retains the authority provided in Appropriations Acts for fiscal years 2014 and 2015 to use CSP funds "for grants that support preschool education in charter schools." For information on the use of CSP funds to support preschool education in charter schools, see "Guidance on the Use of Funds to Support Preschool Education" at *www2.ed.gov/programs/charter/csppreschoolfaqs.doc.*

All charter schools receiving CSP funds, as outlined in section 5210(1)(G) of the ESEA, must comply with various non-discrimination laws, including the Age Discrimination Act of 1975, title VI of the Civil Rights Act of 1964, title IX of the Education Amendments of 1972, section 504 of the Rehabilitation Act of 1973, part B of the Individuals with Disabilities Education Act (specifies rights afforded to students with disabilities and their parents), and applicable State laws.

Priorities: This notice includes two absolute priorities, three competitive preference priorities, and one invitational priority. Both absolute priorities are from the Final Priorities for this program. Part (a) of Competitive Preference Priority 1 is from the Supplemental Priorities; part (b) is from the Final Priorities; and part (c) is from the Promise Zones Priority. Competitive Preference Priority 2 is from the Final Priorities, and Competitive Preference Priority 3 is from 34 CFR 75.225(c)(2).

Absolute Priorities: For FY 2016 and any subsequent year in which we make awards from the list of unfunded applications from this competition, these priorities are absolute priorities. Under 34 CFR 75.105(c)(3), we consider only applications that meet both of the following priorities:

Absolute Priority 1—Experience Operating or Managing High-Quality Charter Schools.

This priority is for projects that will provide for the replication or expansion of high-quality charter schools (as defined in this notice) by applicants that currently operate or manage more than one high-quality charter school (as defined in this notice).

Absolute Priority 2—Low-Income Demographic.

To meet this priority, an applicant must demonstrate that at least 60 percent of all students in the charter schools it currently operates or manages are individuals from low-income families (as defined in this notice).

Competitive Preference Priorities: For FY 2016 and any subsequent year in which we make awards based on the list of unfunded applications from this competition, these priorities are competitive preference priorities. Under 34 CFR 75.105(c)(2)(i), we will award an additional five points to an application that addresses part (a) of Competitive Preference Priority 1; an additional four points to an application that addresses part (b) of Competitive Preference Priority 1; or an additional point to an application that addresses part (c) of Competitive Preference Priority 1. An application may receive points for only one of the three parts of Competitive Preference Priority 1, and should specify which part it is addressing. If an applicant addresses more than one part of Competitive Preference Priority 1 and does not specify whether it is addressing part (a), (b), or (c), the application will be awarded priority points only for the part addressed in the application that has the highest maximum potential point value, regardless of the number of priority points the application is awarded for that particular part of Competitive Preference Priority 1.

We will award an additional three points to an application that meets Competitive Preference Priority 2, and an additional two points to an application that meets Competitive Preference Priority 3. The maximum total competitive preference priority points an application can receive for this competition is 10.

These priorities are:

Competitive Preference Priority 1. (0, 1, 4, or 5 points).

(a) *Supporting High Need Students.* (0 or 5 points).

Projects that are designed to improve academic outcomes, learning environments, or both, for students who are members of federally recognized Indian tribes.

(b) *School Improvement.* (0 or 4 points).

To meet this priority, an applicant must demonstrate that its proposed replication or expansion of one or more high-quality charter schools (as defined in this notice) will occur in partnership with, and will be designed to assist, one or more LEAs in implementing academic or structural interventions to serve students attending schools that have been identified for improvement, corrective action, closure, or restructuring under section 1116 of the ESEA, and as described in the notice of final requirements for School Improvement Grants, published in the **Federal Register** on October 28, 2010 (75 FR 66363).

Note: Applicants in States that are exercising flexibility under the ESEA, as amended by NCLB, in the 2015–16 school year may partner with LEAs to serve students attending priority or focus schools (see the Department's June 7, 2012 guidance entitled, "ESEA Flexibility," at *www.ed.gov/esea/flexibility,* and the Office of Elementary and Secondary Education's (OESE's) December 18, 2015 Dear Colleague Letter at *https://www2.ed.gov/policy/elsec/leg/essa/transition-dcl.pdf*). Applicants in all States should review OESE's January 28, 2016 Dear Colleague Letter at *https://www2.ed.gov/policy/elsec/leg/essa/transitionsy1617-dcl.pdf,* for information on interventions required in 2016–2017.

(c) *Promise Zones.* (0 or 1 point).

This priority is for projects that are designed to serve and coordinate with a federally designated Promise Zone.

Note: As a participant in the Administration's Promise Zones Initiative, the Department is cooperating with the Department of Housing and Urban Development (HUD), the Department of Agriculture (USDA), and nine other Federal agencies to support comprehensive revitalization efforts in 20 high-poverty urban, rural, and tribal communities across the country. Each application for Replication and Expansion grant funds that is accompanied by a Certification of Consistency with Promise Zone Goals and Implementation (HUD Form 50153), signed by an authorized representative of the lead organization of a Promise Zone designated by HUD or USDA supporting the application, will meet this priority. To view the list of designated Promise Zones and lead organizations please go to *www.hud.gov/promisezones.* The certification form is available at *https://portal.hud.gov/hudportal/documents/huddoc?id=HUD_Form_50153.pdf.*

Competitive Preference Priority 2—Promoting Diversity. (0 or 3 points).

This priority is for applicants that demonstrate a record of (in the schools they currently operate or manage), as well as an intent to continue (in schools that they will be creating or substantially expanding (as defined in this notice) under this grant), taking active measures to —

(a) Promote student diversity, including racial and ethnic diversity, or avoid racial isolation;

(b) Serve students with disabilities at a rate that is at least comparable to the rate at which these students are served in public schools in the surrounding area; and

(c) Serve English learners at a rate that is at least comparable to the rate at which these students are served in public schools in the surrounding area.

In support of this priority, applicants must provide enrollment data as well as descriptions of existing policies and activities undertaken or planned to be undertaken.

Note: An applicant addressing Competitive Preference Priority 2 is invited to discuss how the proposed design of its project will encourage approaches by charter schools that help bring together students of different backgrounds, including students from different racial and ethnic backgrounds, to attain the benefits that flow from a diverse student body. The applicant should discuss in its application how it would ensure that those approaches are permissible under current law.

Competitive Preference Priority 3—Novice Applicant. (34 CFR 75.225(c)(2)) (0 or 2 points).

This priority is for applicants that qualify as novice applicants (as defined in this notice).

Invitational Priority: For FY 2016 and any subsequent year in which we make awards based on the list of unfunded applications from this competition, this priority is an invitational priority. Under 34 CFR 75.105(c)(1), we do not give an application that meets this invitational priority any preference over other applications.

This priority is:

Invitational Priority—Rigorous Evaluation.

The Secretary is particularly interested in funding applications that demonstrate that the applicant is currently conducting, or will conduct, a rigorous independent evaluation of specific practices within the applicant's charter schools (*e.g.*, school discipline policies or professional development practices, such as teacher coaching), through a quasi-experimental design study or randomized controlled trial (as defined in this notice) that will, if well implemented, meet What Works Clearinghouse (WWC) Evidence Standards (as defined in this notice).

The following definitions are from 34 CFR 75.225 and 77.1 and the Final Priorities for this program.

Ambitious means promoting continued, meaningful improvement for program participants or for other individuals or entities affected by the grant, or representing a significant advancement in the field of education research, practices, or methodologies. When used to describe a performance target (as defined in this notice), whether a performance target (as defined in this notice) is ambitious depends upon the context of the relevant performance measure (as defined in this notice) and the baseline (as defined in this notice) for that measure. (34 CFR 77.1)

Baseline means the starting point from which performance is measured and targets are set. (34 CFR 77.1)

Charter management organization (CMO) is a nonprofit organization that operates or manages multiple charter schools by centralizing or sharing certain functions and resources among schools. (Final Priorities)

Educationally disadvantaged students includes, but is not necessarily limited to, individuals from low-income families (as defined in this notice), English learners, migratory children, children with disabilities, and neglected or delinquent children. (Final Priorities)

High-quality charter school is a school that shows evidence of strong academic results for the past three years (or over the life of the school, if the school has been open for fewer than three years), based on the following factors:

(1) Increasing student academic achievement and attainment for all students, including, as applicable, educationally disadvantaged students (as defined in this notice) served by the charter schools operated or managed by the applicant.

(2) Either (i) Demonstrated success in closing historic achievement gaps for the subgroups of students described in section 1111(b)(2)(C)(v)(II) of the ESEA at the charter schools operated or managed by the applicant, or

(ii) No significant achievement gaps between any of the subgroups of students described in section 1111(b)(2)(C)(v)(II) of the ESEA at the charter schools operated or managed by the applicant and significant gains in student academic achievement with all populations of students served by the charter schools operated or managed by the applicant.

(3) Achieved results (including performance on statewide tests, annual student attendance and retention rates, high school graduation rates, college attendance rates, and college persistence rates where applicable and available) for low-income and other educationally disadvantaged students (as defined in this notice) served by the charter schools operated or managed by the applicant that are above the average academic achievement results for such students in the State.

(4) No significant compliance issues (as defined in this notice), particularly in the areas of student safety and financial management. (Final Priorities)

Individual from a low-income family means an individual who is determined by a State educational agency (SEA) or LEA to be a child, age 5 through 17, from a low-income family on the basis of (a) data used by the Secretary to determine allocations under section 1124 of the ESEA, (b) data on children eligible for free or reduced-price lunches under the Richard B. Russell National School Lunch Act, (c) data on children in families receiving assistance under part A of title IV of the Social Security Act, (d) data on children eligible to receive medical assistance under the Medicaid program under Title XIX of the Social Security Act, or (e) an alternate method that combines or extrapolates from the data in items (a) through (d) of this definition (see 20 U.S.C. 6537(3)). (Final Priorities)

Novice applicant means—

(a) Any applicant for a grant from the Department that—

(i) Has never received a grant or subgrant under the program from which it seeks funding;

(ii) Has never been a member of a group application, submitted in accordance with 34 CFR 75.127–75.129, that received a grant under the program from which it seeks funding; and

(iii) Has not had an active discretionary grant from the Federal government in the five years before the deadline date for applications for new awards under the program.

(b) For purposes of paragraph (a)(1)(iii) of this section, a grant is active until the end of the grant's project or funding period, including any extensions of those periods that extend the grantee's authority to obligate funds (34 CFR 75.225).

Performance measure means any quantitative indicator, statistic, or metric used to gauge program or project performance. (34 CFR 77.1)

Performance target means a level of performance that an applicant would seek to meet during the course of a project or as a result of a project. (34 CFR 77.1)

Quasi-experimental design study means a study using a design that attempts to approximate an experimental design by identifying a comparison group that is similar to the treatment group in important respects. These studies, depending on design and implementation, can meet What Works Clearinghouse Evidence Standards with reservations (but not What Works Clearinghouse Evidence Standards without reservations). (34 CFR 77.1)

Randomized controlled trial means a study that employs random assignment of, for example, students, teachers, classrooms, schools, or districts to receive the intervention being evaluated (the treatment group) or not to receive the intervention (the control group). The estimated effectiveness of the intervention is the difference between the average outcome for the treatment group and for the control group. These studies, depending on design and implementation, can meet What Works Clearinghouse Evidence Standards (as defined in this notice) without reservations. (34 CFR 77.1)

Replicate means to open one or more new charter schools that are based on the charter school model or models for which the applicant has presented evidence of success. (Final Priorities)

Significant compliance issue means a violation that did, will, or could lead to the revocation of a school's charter. (Final Priorities)

Substantially expand means to increase the student count of an existing charter school by more than 50 percent or to add at least two grades to an existing charter school over the course of the grant. (Final Priorities)

What Works Clearinghouse Evidence Standards means the standards set forth in the What Works Clearinghouse Procedures and Standards Handbook (Version 3.0, March 2014), which can be found at the following link: *//ies.ed.gov/ncee/wwc/DocumentSum.aspx?sid=19.* (34 CFR 77.1)

Program Authority: FY 2016 Appropriations Act; and the ESEA, as amended by NCLB (20 U.S.C. 7221–7221j).

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 75, 76, 77, 79, 81, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended in 2 CFR part 3474. (d) The Final Priorities for this program. (e) The Promise Zones Priority. (f) The Supplemental Priorities.

Note 1: The regulations in 34 CFR part 79 apply to all applicants except federally recognized Indian tribes.

Note 2: The regulations in 34 CFR part 86 apply only to institutions of higher education.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: $65,000,000.

Estimated Range of Awards: $500,000 to $3,000,000 per year.

Estimated Average Size of Awards: $1,600,000 per year.

Estimated Number of Awards: 10–20.

Note: The Department is not bound by any estimates in this notice. The estimated range and average size of awards are based on a single 12-month budget period.

Project Period: Up to 60 months.

Maximum Award: See *Reasonable and Necessary Costs* in section III.3.(a) below for information regarding the maximum amount of funds that may be awarded per new school seat and per new school.

III. Eligibility Information

1. *Eligible Applicants:* Non-profit charter management organizations (as defined in this notice) and other entities that are not for-profit entities. Eligible applicants also may apply as a group or consortium.

2. *Cost Sharing or Matching:* This competition does not require cost sharing or matching.

3. *Other:* (a) *Reasonable and Necessary Costs:* The Secretary may elect to impose maximum limits on the amount of grant funds that may be awarded per charter school replicated (as defined in this notice), per charter school substantially expanded (as defined in this notice), or per new school seat created.

For this competition, the maximum limit of grant funds that may be awarded per new school seat is $3,000, including a maximum limit per new school created of $800,000. The maximum limit per new school seat in a charter school that is substantially expanding (as defined in this notice) its enrollment is $1,500, including a maximum limit per substantially expanded (as defined in this notice) school of $800,000.

Note: Applicants must ensure that all costs included in the proposed budget are reasonable and necessary in light of the goals and objectives of the proposed project. Any costs determined by the Secretary to be unreasonable or unnecessary will be removed from the final approved budget.

(b) *Other CSP Grants:* A charter school that has received CSP funds for replication or expansion previously, or that has received funds for planning or initial implementation of a charter school (*i.e.,* CFDA 84.282A or 84.282B), may not use funds under this grant for the same purpose. However, such charter school may be eligible to receive funds under this competition to substantially expand the charter school beyond the existing grade levels or student count.

A charter school that receives funds under this competition is ineligible to receive funds for the same purpose under section 5202(c)(2) of the ESEA, including for planning and program design or the initial implementation of a charter school (*i.e.,* CFDA 84.282A or 84.282B).

(c) *Costs for Evaluation.* In accordance with 34 CFR 75.590, Replication and Expansion grant funds may be used to cover post-award costs associated with an evaluation under the invitational priority or an evaluation under Selection Criterion (e) of this notice, provided that such costs are reasonable and necessary to meet the objectives of the approved project.

IV. Application and Submission Information

1. *Address To Request Application Package:* Brian Martin, U.S. Department of Education, 400 Maryland Avenue SW., Room 4W224, Washington, DC 20202–5970. Telephone: (202) 205–9085 or by email: *brian.martin@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

Individuals with disabilities can obtain a copy of the application package in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) by contacting the program contact person listed in this section.

2.a. *Content and Form of Application Submission:* Requirements concerning the content of an application, together with the forms you must submit, are in the application package for this competition.

Page Limit: The application narrative (Part III of the application) is where you, the applicant, address the priorities, selection criteria, and application requirements that reviewers use to evaluate your application. We recommend that you limit the application narrative [Part III] to no more than 60 pages, using the following standards:

- A "page" is 8.5″ x 11″, on one side only, with 1″ margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions, as well as all text in charts, tables, figures, and graphs.
- Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial. An application submitted in any other font (including Times Roman or Arial Narrow) will not be accepted.

The page limit does not apply to Part I, the cover sheet; Part II, the budget section, including the narrative budget justification; Part IV, the assurances and certifications; or the one-page abstract, the resumes, the bibliography, or the letters of support. However, the page limit does apply to all of the application narrative section (Part III).

b. *Submission of Proprietary Information:*

Given the types of projects that may be proposed in applications for the Replication and Expansion grant competition, your application may include business information that you consider proprietary. In 34 CFR 5.11 we define "business information" and describe the process we use in determining whether any of that information is proprietary and, thus, protected from disclosure under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552, as amended).

Because we plan to make successful applications available to the public, you may wish to request confidentiality of business information.

Consistent with Executive Order 12600, please designate in your application any information that you feel is exempt from disclosure under Exemption 4. In the appropriate Appendix section of your application, under "Other Attachments Form," please list the page number or numbers on which we can find this information. For additional information please see 34 CFR 5.11(c).

3. *Submission Dates and Times:*

Applications Available: May 10, 2016.

Date of Pre-Application Webinar: The Department will hold a pre-application meeting via Webinar for prospective applicants on June 16, 2016, 2:00 p.m. to 3:30 p.m., Washington, DC, time. Individuals interested in attending this meeting are encouraged to pre-register by emailing their name, organization, and contact information with the subject heading "PRE-APPLICATION MEETING" to *CharterSchools@ed.gov*. There is no registration fee for attending this meeting.

For further information about the pre-application meeting, contact Brian Martin, U.S. Department of Education, 400 Maryland Avenue SW., Room 4W224, Washington, DC 20202–5970. Telephone: (202) 205–9085 or by email: *brian.martin@ed.gov*.

Deadline for Transmittal of Applications: June 24, 2016.

Applications for grants under this competition must be submitted electronically using the Grants.gov Apply site (Grants.gov). For information (including dates and times) about how to submit your application electronically, or in paper format by mail or hand delivery if you qualify for an exception to the electronic submission requirement, please refer to *Other Submission Requirements* in section IV of this notice.

We do not consider an application that does not comply with the deadline requirements.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice. If the Department provides an accommodation or auxiliary aid to an individual with a disability in connection with the application process, the individual's application remains subject to all other requirements and limitations in this notice.

Deadline for Intergovernmental Review: August 23, 2016.

4. *Intergovernmental Review:* This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this competition.

5. *Funding Restrictions:* Grantees under this program must use the grant funds to replicate (as defined in this notice) or substantially expand (as defined in this notice) the charter school model or models for which the applicant has presented evidence of success. Grant funds must be used to carry out allowable activities, as described in section 5204(f)(3) of the ESEA (20 U.S.C. 7221c(f)(3)).

Pursuant to section 5204(f)(3) of the ESEA, grantees under this program must use the grant funds for—

(a) Post-award planning and design of the educational program, which may include: (i) Refinement of the desired educational results and of the methods for measuring progress toward achieving those results; and (ii) professional development of teachers and other staff who will work in the charter school; and

(b) Initial implementation of the charter school, which may include: (i) Informing the community about the school; (ii) acquiring necessary equipment and educational materials and supplies; (iii) acquiring or developing curriculum materials; and (iv) other initial operational costs that cannot be met from State or local sources.

The FY 2016 Appropriations Act authorizes the use of CSP funds "for grants that support preschool education in charter schools." Therefore, an application submitted under this competition may propose to use CSP funds to support preschool education in a charter school. For additional information and guidance regarding the use of CSP funds to support preschool education in charter schools, see "Guidance on the use of Funds to support Preschool Education," released in November 2014 (*www2.ed.gov/programs/charter/csppreschoolfaqs.doc*).

In accordance with the program requirements from the Final Priorities, a grantee may use up to 20 percent of grant funds for initial operational costs associated with the expansion or improvement of the grantee's oversight or management of its charter schools, provided that: (i) The specific charter schools being created or substantially expanded (as defined in this notice) under the grant are the intended beneficiaries of such expansion or improvement, and (ii) such expansion or improvement is intended to improve the grantee's ability to manage or oversee the charter schools created or substantially expanded under the grant.

We reference additional regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

6. *Data Universal Numbering System Number, Taxpayer Identification Number, and System for Award Management:* To do business with the Department of Education, you must—

a. Have a Data Universal Numbering System (DUNS) number and a Taxpayer Identification Number (TIN);

b. Register both your DUNS number and TIN with the System for Award Management (SAM) (formerly the Central Contractor Registry), the Government's primary registrant database;

c. Provide your DUNS number and TIN on your application; and

d. Maintain an active SAM registration with current information while your application is under review by the Department and, if you are awarded a grant, during the project period.

You can obtain a DUNS number from Dun and Bradstreet at the following Web site: *http://fedgov.dnb.com/webform*. A DUNS number can be created within one to two business days.

If you are a corporate entity, agency, institution, or organization, you can obtain a TIN from the Internal Revenue Service. If you are an individual, you can obtain a TIN from the Internal Revenue Service or the Social Security Administration. If you need a new TIN, please allow two to five weeks for your TIN to become active.

The SAM registration process can take approximately seven business days, but may take upwards of several weeks, depending on the completeness and accuracy of the data you enter into the SAM database. Thus, if you think you might want to apply for Federal financial assistance under a program administered by the Department, please allow sufficient time to obtain and register your DUNS number and TIN. We strongly recommend that you register early.

Note: Once your SAM registration is active, it may be 24 to 48 hours before you can access the information in, and submit an application through, Grants.gov.

If you are currently registered with SAM, you may not need to make any changes. However, please make certain that the TIN associated with your DUNS number is correct. Also note that you will need to update your registration annually. This may take three or more business days.

Information about SAM is available at *www.SAM.gov.* To further assist you with obtaining and registering your DUNS number and TIN in SAM or updating your existing SAM account, we have prepared a SAM.gov Tip Sheet, which you can find at: *www2.ed.gov/fund/grant/apply/sam-faqs.html.*

In addition, if you are submitting your application via Grants.gov, you must (1) be designated by your organization as an Authorized Organization Representative (AOR); and (2) register yourself with Grants.gov as an AOR. Details on these steps are outlined at the following Grants.gov Web page: *www.grants.gov/web/grants/register.html.*

7. *Other Submission Requirements.* Applications for grants under this competition must be submitted electronically unless you qualify for an exception to this requirement in accordance with the instructions in this section.

a. *Electronic Submission of Applications.*

Applications for grants under the CSP Grants for Replication and Expansion of High-Quality Charter Schools, CFDA number 84.282M, must be submitted electronically using the Governmentwide Grants.gov Apply site at *www.Grants.gov.* Through this site, you will be able to download a copy of the application package, complete it offline, and then upload and submit your application. You may not email an electronic copy of a grant application to us.

We will reject your application if you submit it in paper format unless, as described elsewhere in this section, you qualify for one of the exceptions to the electronic submission requirement *and* submit, no later than two weeks before the application deadline date, a written statement to the Department that you qualify for one of these exceptions. Further information regarding calculation of the date that is two weeks before the application deadline date is provided later in this section under *Exception to Electronic Submission Requirement.*

You may access the electronic grant application for CSP Grants for Replication and Expansion of High-Quality Charter Schools at *www.Grants.gov.* You must search for the downloadable application package for this competition by the CFDA number. Do not include the CFDA number's alpha suffix in your search (*e.g.,* search for 84.282, not 84.282M).

Please note the following:

- When you enter the Grants.gov site, you will find information about submitting an application electronically through the site, as well as the hours of operation.
- Applications received by Grants.gov are date and time stamped. Your application must be fully uploaded and submitted and must be date and time stamped by the Grants.gov system no later than 4:30:00 p.m., Washington, DC time, on the application deadline date. Except as otherwise noted in this section, we will not accept your application if it is received—that is, date and time stamped by the Grants.gov system—after 4:30:00 p.m., Washington, DC time, on the application deadline date. We do not consider an application that does not comply with the deadline requirements. When we retrieve your application from Grants.gov, we will notify you if we are rejecting your application because it was date and time stamped by the Grants.gov system after 4:30:00 p.m., Washington, DC time, on the application deadline date.
- The amount of time it can take to upload an application will vary depending on a variety of factors, including the size of the application and the speed of your Internet connection. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the submission process through Grants.gov.
- You should review and follow the Education Submission Procedures for submitting an application through Grants.gov that are included in the application package for this competition to ensure that you submit your application in a timely manner to the Grants.gov system. You can also find the Education Submission Procedures pertaining to Grants.gov under News and Events on the Department's G5 system home page at *www.G5.gov.* In addition, for specific guidance and procedures for submitting an application through Grants.gov, please refer to the Grants.gov Web site at: *www.grants.gov/web/grants/applicants/apply-for-grants.html.*
- You will not receive additional point value because you submit your application in electronic format, nor will we penalize you if you qualify for an exception to the electronic submission requirement, as described elsewhere in this section, and submit your application in paper format.
- You must submit all documents electronically, including all information you typically provide on the following forms: the Application for Federal Assistance (SF 424), the Department of Education Supplemental Information for SF 424, Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications.
- You must upload any narrative sections and all other attachments to your application as files in a read-only, non-modifiable Portable Document Format (PDF). Do not upload an interactive or fillable PDF file. If you upload a file type other than a read-only, non-modifiable PDF (*e.g.,* Word, Excel, WordPerfect, etc.) or submit a password-protected file, we will not review that material. Please note that this could result in your application not being considered for funding because the material in question—for example, the project narrative—is critical to a meaningful review of your proposal. For that reason it is important to allow yourself adequate time to upload all material as PDF files. The Department will not convert material from other formats to PDF.
- Your electronic application must comply with any page-limit requirements described in this notice.
- After you electronically submit your application, you will receive from Grants.gov an automatic notification of receipt that contains a Grants.gov tracking number. This notification indicates receipt by Grants.gov only, not receipt by the Department. Grants.gov will also notify you automatically by email if your application met all the Grants.gov validation requirements or if there were any errors (such as submission of your application by someone other than a registered Authorized Organization Representative, or inclusion of an attachment with a file name that contains special characters). You will be given an opportunity to correct any errors and resubmit, but you must still meet the deadline for submission of applications.

Once your application is successfully validated by Grants.gov, the Department will retrieve your application from Grants.gov and send you an email with a unique PR/Award number for your application.

These emails do not mean that your application is without any disqualifying errors. While your application may have been successfully validated by Grants.gov, it must also meet the Department's application requirements as specified in this notice and in the application instructions. Disqualifying errors could include, for instance, failure to upload attachments in a read-only, non-modifiable PDF; failure to submit a required part of the application; or failure to meet applicant eligibility requirements. It is your responsibility to ensure that your submitted application has met all of the Department's requirements.

- We may request that you provide us original signatures on forms at a later date.

Application Deadline Date Extension in Case of Technical Issues with the Grants.gov System: If you are experiencing problems submitting your application through Grants.gov, please contact the Grants.gov Support Desk, toll free, at 1–800–518–4726. You must obtain a Grants.gov Support Desk Case Number and must keep a record of it.

If you are prevented from electronically submitting your application on the application deadline date because of technical problems with the Grants.gov system, we will grant you an extension until 4:30:00 p.m., Washington, DC time, the following business day to enable you to transmit your application electronically or by hand delivery. You also may mail your application by following the mailing instructions described elsewhere in this notice.

If you submit an application after 4:30:00 p.m., Washington, DC time, on the application deadline date, please contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice and provide an explanation of the technical problem you experienced with Grants.gov, along with the Grants.gov Support Desk Case Number. We will accept your application if we can confirm that a technical problem occurred with the Grants.gov system and that the problem affected your ability to submit your application by 4:30:00 p.m., Washington, DC time, on the application deadline date. We will contact you after we determinate whether your application will be accepted.

Note: The extensions to which we refer in this section apply only to the unavailability of, or technical problems with, the Grants.gov system. We will not grant you an extension if you failed to fully register to submit your application to Grants.gov before the application deadline date and time or if the technical problem you experienced is unrelated to the Grants.gov system.

Exception to Electronic Submission Requirement: You qualify for an exception to the electronic submission requirement, and may submit your application in paper format, if you are unable to submit an application through the Grants.gov system because—

- You do not have access to the Internet; or
- You do not have the capacity to upload large documents to the Grants.gov system;

and

- No later than two weeks before the application deadline date (14 calendar days or, if the fourteenth calendar day before the application deadline date falls on a Federal holiday, the next business day following the Federal holiday), you mail or fax a written statement to the Department, explaining which of the two grounds for an exception prevents you from using the Internet to submit your application.

If you mail your written statement to the Department, it must be postmarked no later than two weeks before the application deadline date. If you fax your written statement to the Department, we must receive the faxed statement no later than two weeks before the application deadline date.

Address and mail or fax your statement to: Brian Martin, U.S. Department of Education, 400 Maryland Avenue SW., Room 4W224, Washington, DC 20202–5970. FAX: (202) 205–5630.

Your paper application must be submitted in accordance with the mail or hand delivery instructions described in this notice.

b. *Submission of Paper Applications by Mail.*

If you qualify for an exception to the electronic submission requirement, you may mail (through the U.S. Postal Service or a commercial carrier) your application to the Department. You must mail the original and two copies of your application, on or before the application deadline date, to the Department at the following address:

U.S. Department of Education,
Application Control Center,
Attention: CFDA Number 84.282M,
LBJ Basement Level 1, 400 Maryland Avenue SW., Washington, DC 20202–4260.

You must show proof of mailing consisting of one of the following:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

(1) A private metered postmark.

(2) A mail receipt that is not dated by the U.S. Postal Service.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

We will not consider applications postmarked after the application deadline.

c. *Submission of Paper Applications by Hand Delivery.*

If you qualify for an exception to the electronic submission requirement, you (or a courier service) may deliver your paper application to the Department by hand. You must deliver the original and two copies of your application by hand, on or before the application deadline date, to the Department at the following address:

U.S. Department of Education,
Application Control Center,
Attention: CFDA Number 84.282M,
550 12th Street SW., Room 7039,
Potomac Center Plaza, Washington, DC 20202–4260.

The Application Control Center accepts hand deliveries daily between 8:00 a.m. and 4:30 p.m., Washington, DC time, except Saturdays, Sundays, and Federal holidays.

Note for Mail or Hand Delivery of Paper Applications: If you mail or hand deliver your application to the Department—

(1) You must indicate on the envelope and—if not provided by the Department—in Item 11 of the SF 424 the CFDA number, including suffix letter, if any, of the competition under which you are submitting your application; and

(2) The Application Control Center will mail to you a notification of receipt of your grant application. If you do not receive this notification within 15 business days from the application deadline date, you should call the U.S. Department of Education Application Control Center at (202) 245–6288.

V. Application Review Information

1. *Application Requirements:* Applications for CSP Replication and Expansion grant funds must address the following application requirements. An applicant may choose to respond to the application requirements in the context of its responses to the selection criteria.

These application requirements are from the Final Priorities for this program.

(a) Describe the objectives of the project for replicating or substantially expanding high-quality charter schools (as defined in this notice) and the methods by which the applicant will determine its progress toward achieving those objectives.

(b) Describe how the applicant currently operates or manages the charter schools for which it has presented evidence of success, and how the proposed new or substantially expanded (as defined in this notice) charter schools will be operated or managed. Include a description of central office functions, governance, daily operations, financial management, human resources management, and instructional management. If applying as a group or consortium, describe the roles and responsibilities of each member of the group or consortium and how each member will contribute to this project.

(c) Describe how the applicant will ensure that each proposed new or substantially expanded charter school receives its commensurate share of Federal education funds that are allocated by formula each year, including during the first year of operation of the school and any year in which the school's enrollment substantially expands (as defined in this notice).

(d) Describe the educational program to be implemented in the proposed new or substantially expanded charter schools, including how the program will enable all students (including educationally disadvantaged students (as defined in this notice)) to meet State student academic achievement standards, the grade levels or ages of students to be served, and the curriculum and instructional practices to be used.

Note: As part of the grants review process, an applicant currently operating or proposing to create or substantially expand (as defined in this notice) a single-sex charter school, or an applicant currently providing or proposing to provide a single-sex class or single-sex extracurricular activity within a coeducational charter school (collectively referred to as "single-sex educational program"), must demonstrate that its existing or proposed single-sex educational program is in compliance with applicable nondiscrimination laws, including the Equal Protection Clause of the U.S. Constitution (as interpreted in United States v. Virginia, 518 U.S. 515 (1996), and other cases) and Title IX of the Education Amendments of 1972 (20 U.S.C. 1681, *et seq.*) and its regulations, including 34 CFR 106.34. Such an applicant likely will be required to provide fact-specific information about the single-sex educational program within specified timeframes. In addition, special conditions are likely to be placed on any grant awarded to an applicant that provides a single-sex educational program. Please see the application package for additional information related to the requirements for single-sex educational programs.

(e) Describe the administrative relationship between the charter school or schools to be replicated (as defined in this notice) or substantially expanded (as defined in this notice) by the applicant and the authorized public chartering agency.

(f) Describe how the applicant will provide for continued operation of the proposed new or substantially expanded charter school or schools once the Federal grant has expired.

(g) Describe how parents and other members of the community will be involved in the planning, program design, and implementation of the proposed new or substantially expanded (as defined in this notice) charter school or schools.

(h) Include a request and justification for waivers of any Federal statutory or regulatory provisions that the applicant believes are necessary for the successful operation of the proposed new or substantially expanded charter schools.

(i) Describe how the grant funds will be used, including how these funds will be used in conjunction with other Federal programs administered by the Secretary, and with any matching funds.

(j) Describe how all students in the community, including students with disabilities, English learners, and other educationally disadvantaged students (as defined in this notice), will be informed about the proposed new or substantially expanded (as defined in this notice) charter schools and given an equal opportunity to attend such schools.

Note: Under section 5210(1)(H) of the ESEA (20 U.S.C. 7221i(1)(H)), charter schools receiving CSP funds must admit students on the basis of a lottery if more students apply for admission than can be accommodated. Accordingly, the application must include a description of the applicant's admissions policy, including the lottery that will be employed by each charter school that is oversubscribed.

(k) Describe how the proposed new or substantially expanded charter schools that are considered to be LEAs under State law, or the LEAs in which the new or substantially expanded (as defined in this notice) charter schools are located, will comply with sections 613(a)(5) and 613(e)(1)(B) of the Individuals with Disabilities Education Act (IDEA).

(l) Provide information on any significant compliance issues (as defined in this notice) identified within the past three years for each school managed by the applicant, including compliance issues in the areas of student safety, financial management, and statutory or regulatory compliance.

(m) For each charter school currently operated or managed by the applicant, provide the following information: The year founded, the grades currently served, the number of students, the address, the percentage of students in each subgroup of students described in section 1111(b)(2)(C)(v)(II) of the ESEA, results on the State assessment for the past three years (if available) by subgroup, attendance rates, student attrition rates for the past three years, and (if the school operates a 12th grade) high school graduation rates and college attendance rates (maintaining standards to protect personally identifiable information).

(n) Provide objective data showing applicant quality. In particular, the Secretary requires the applicant to provide the following data:

(1) Performance (school-wide and by subgroup) for the past three years (if available) on statewide tests of all charter schools operated or managed by the applicant as compared to all students in other schools in the State or States at the same grade level, and as compared with other schools serving similar demographics of students (maintaining standards to protect personally identifiable information);

(2) Annual student attendance and retention rates (school-wide and by subgroup) for the past three years (or over the life of the school, if the school has been open for fewer than three years), and comparisons with other similar schools (maintaining standards to protect personally identifiable information); and

(3) Where applicable and available, high school graduation rates, college attendance rates, and college persistence rates (school-wide and by subgroup) for the past three years (if available) of students attending schools operated or managed by the applicant, and the methodology used to calculate these rates (maintaining standards to protect personally identifiable information). When reporting data for schools in States that may have particularly demanding or low standards of proficiency, applicants are invited to discuss how their academic success might be considered against applicants from across the country.

(o) Provide such other information and assurances as the Secretary may require.

2. *Selection Criteria.* The selection criteria for this program are from the Final Priorities for this program and 34 CFR 75.210. The maximum possible score for addressing all of the criteria in this section is 100 points. The maximum possible score for addressing

each criterion is indicated in parentheses following the criterion.

In evaluating an application, the Secretary considers the following criteria:

(a) *Quality of the eligible applicant.* (Final Priorities) (50 points)

In determining the quality of the applicant, the Secretary considers the following factors—

(1) The degree, including the consistency over the past three years, to which the applicant has demonstrated success in significantly increasing student academic achievement and attainment for all students, including, as applicable, educationally disadvantaged students (as defined in this notice) served by the charter schools operated or managed by the applicant (20 points).

(2) Either—

(i) The degree, including the consistency over the past three years, to which the applicant has demonstrated success in closing historic achievement gaps for the subgroups of students described in section 1111(b)(2)(C)(v)(II) of the ESEA at the charter schools operated or managed by the applicant, or

(ii) The degree, including the consistency over the past three years, to which there have not been significant achievement gaps between any of the subgroups of students described in section 1111(b)(2)(C)(v)(II) of the ESEA at the charter schools operated or managed by the applicant and to which significant gains in student academic achievement have been made with all populations of students served by the charter schools operated or managed by the applicant (15 points).

(3) The degree, including the consistency over the past three years, to which the applicant has achieved results (including performance on statewide tests, annual student attendance and retention rates, high school graduation rates, college attendance rates, and college persistence rates where applicable and available) for low-income and other educationally disadvantaged students (as defined in this notice) served by the charter schools operated or managed by the applicant that are significantly above the average academic achievement results for such students in the State (15 points).

(b) *Contribution in assisting educationally disadvantaged students.* (Final Priorities) (10 points)

The contribution the proposed project will make in assisting educationally disadvantaged students (as defined in this notice) served by the applicant to meet or exceed State academic content standards and State student academic achievement standards, and to graduate college- and career-ready. When responding to this selection criterion, applicants must discuss the proposed locations of schools to be created or substantially expanded and the student populations to be served.

(c) *Quality of the project design.* (Final Priorities) (10 points) The Secretary considers the quality of the design of the proposed project. In determining the quality of the design of the proposed project, the Secretary considers the extent to which the goals, objectives, and outcomes to be achieved by the proposed project are clearly specified, measurable, and attainable. Applicants proposing to open schools serving substantially different populations than those currently served by the model for which they have demonstrated evidence of success must address the attainability of outcomes given this difference.

(d) *Quality of the management plan and personnel.* (Final Priorities) (20 points)

The Secretary considers the quality of the management plan and personnel to replicate and substantially expand high-quality charter schools (as defined in this notice). In determining the quality of the management plan and personnel for the proposed project, the Secretary considers—

(1) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks (4 points).

(2) The business plan for improving, sustaining, and ensuring the quality and performance of charter schools created or substantially expanded (as defined in this notice) under these grants beyond the initial period of Federal funding in areas including, but not limited to, facilities, financial management, central office, student academic achievement, governance, oversight, and human resources of the charter schools (4 points).

(3) A multi-year financial and operating model for the organization, a demonstrated commitment of current and future partners, and evidence of broad support from stakeholders critical to the project's long-term success (4 points).

(4) The plan for closing charter schools supported, overseen, or managed by the applicant that do not meet high standards of quality (2 points).

(5) The qualifications, including relevant training and experience, of the project director, chief executive officer or organization leader, and key project personnel, especially in managing projects of the size and scope of the proposed project (6 points).

(e) *Quality of the evaluation plan.* (34 CFR 75.210(h)(2)(iv)) (10 points)

The Secretary considers the quality of the evaluation to be conducted of the proposed project. In determining the quality of the evaluation, the Secretary considers the extent to which the methods of evaluation include the use of objective performance measures (as defined in this notice) that are clearly related to the intended outcomes of the project and will produce quantitative and qualitative data to the extent possible.

3. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department of Education (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

4. *Risk Assessment and Special Conditions:* Consistent with 2 CFR 200.205, before awarding grants under this competition the Department conducts a review of the risks posed by applicants. Under 2 CFR 3474.10, the Secretary may impose special conditions and, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

(c) Under 34 CFR 75.250(b), the Secretary may provide a grantee with additional funding for data collection analysis and reporting. In this case the Secretary establishes a data collection period.

4. *Performance Measures:* (a) The goal of the CSP is to support the creation and development of a large number of high-quality charter schools (as defined in this notice) that are free from State or local rules that inhibit flexible operation, are held accountable for enabling students to reach challenging State performance standards, and are open to all students. The Secretary has two performance indicators to measure progress towards this goal: (1) The number of charter schools in operation around the Nation, and (2) the percentage of fourth- and eighth-grade charter school students who are achieving at or above the proficient level on State assessments in mathematics and reading/language arts. Additionally, the Secretary has established the following measure to examine the efficiency of the CSP: Federal cost per student in implementing a successful school (defined as a school in operation for three or more consecutive years).

(b) *Project-Specific Performance Measures.* Applicants must propose project-specific performance measures (as defined in this notice) and performance targets (as defined in this notice) consistent with the objectives of the proposed project. Applications must provide the following information as directed under 34 CFR 75.110(b) and (c):

(1) *Performance measures.* How each proposed performance measure (as defined in this notice) would accurately measure the performance of the project and how the proposed performance measure (as defined in this notice) would be consistent with the performance measures (as defined in this notice) established for the program funding the competition.

(2) *Baseline data.* (i) Why each proposed baseline (as defined in this notice) is valid; or (ii) if the applicant has determined that there are no established baseline (as defined in this notice) data for a particular performance measure (as defined in this notice), an explanation of why there is no established baseline (as defined in this notice) and of how and when, during the project period, the applicant would establish a valid baseline (as defined in this notice) for the performance measure (as defined in this notice).

(3) *Performance targets.* Why each proposed performance target (as defined in this notice) is ambitious (as defined in this notice) yet achievable compared to the baseline (as defined in this notice) for the performance measure (as defined in this notice) and when, during the project period, the applicant would meet the performance target(s) (as defined in this notice).

(4) The applicant must also describe in the application: (i) The data collection and reporting methods the applicant would use and why those methods are likely to yield reliable, valid, and meaningful performance data, and (ii) the applicant's capacity to collect and report reliable, valid, and meaningful performance data, as evidenced by high-quality data collection, analysis, and reporting in other projects or research.

All grantees must submit an annual performance report with information that is responsive to these performance measures (as defined in this notice).

5. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things: Whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, the performance targets (as defined in this notice) in the grantee's approved application.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Agency Contact

FOR FURTHER INFORMATION CONTACT: Brian Martin, U.S. Department of Education, 400 Maryland Avenue SW., Room 4W224, Washington, DC 20202–5970. Telephone: (202) 205–9085 or by email: *brian.martin@ed.gov.*

If you use a TDD or a TTY, call the FRS, toll free, at 1–800–877–8339.

VIII. Other Information

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (*e.g.*, braille, large print, audiotape, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: May 5, 2016.

Nadya Chinoy Dabby,

Assistant Deputy Secretary for Innovation and Improvement.

[FR Doc. 2016–10925 Filed 5–9–16; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

U.S. Energy Information Administration

Agency Information Collection Extension

AGENCY: U.S. Energy Information Administration (EIA), Department of Energy.

ACTION: Notice and request for OMB review and comment.

SUMMARY: The EIA has submitted an information collection request to the OMB for extension under the provisions of the Paperwork Reduction Act of 1995. The information collection requests a three-year extension with changes for Form FE–746R, "Natural Gas Imports and Exports," OMB Control Number 1901–0294. The proposed collection will support DOE's Office of Fossil Energy (FE) in the collection of critical information on U.S. natural gas trade. Data collected include name of importer/exporter; country of origin/destination; international point of entry/exit; name of supplier; volume; price; transporters; U.S. geographic market(s) served; and duration of supply contract on a monthly basis. The data, published in *Natural Gas Imports and Exports,* are used to monitor North American gas trade, and to support various market and regulatory analyses done by FE.

DATES: Comments regarding this proposed information collection must be received on or before June 9, 2016. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, please advise the DOE Desk Officer at OMB of your intention to make a submission as soon as possible. The Desk Officer may be telephoned at 202–395–4718.

ADDRESSES: Written comments should be sent to the:

DOE Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10102, 735 17th Street NW., Washington, DC 20503

And to

Benjamin Nussdorf, U.S. Department of Energy (FE–34), Office of Regulation and International Engagement, Office of Fossil Energy, Forrestal Building, Room 3E–042, 1000 Independence Avenue SW., Washington, DC 20585, (P) (202) 586–7893, (F) (202) 586–6050, *Benjamin.nussdorf@hq.doe.gov*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Benjamin Nussdorf at the contact information above. Copies of the information collection instruments and instructions can also be viewed at *http://energy.gov/fe/services/natural-gas-regulation/guidelines-filing-monthly-reports.*

SUPPLEMENTARY INFORMATION:

This information collection request contains:

(1) OMB No. 1901–0294;

(2) *Information Collection Request Title:* Natural Gas Imports and Exports;

(3) *Type of Request:* Three year extension with changes;

(4) *Purpose:* The Federal Energy Administration Act of 1974 (15 U.S.C. 761 *et seq.*) and the DOE Organization Act (42 U.S.C. 7101 *et seq.*) require the EIA to carry out a centralized, comprehensive, and unified energy information program. This program collects, evaluates, assembles, analyzes, and disseminates information on energy resource reserves, production, demand, technology, and related economic and statistical information. This information is used to assess the adequacy of energy resources to meet near and longer term domestic demands.

The EIA, as part of its effort to comply with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), provides the general public and other Federal agencies with opportunities to comment on collections of energy information conducted by or in conjunction with the EIA. Also, the EIA will later seek approval by the Office of Management and Budget (OMB) under section 3507(a) of the Paperwork Reduction Act of 1995.

DOE's Office of Fossil Energy (FE) is authorized to regulate natural gas imports and exports and require the filing of reports under section 3 of the Natural Gas Act of 1938 and 15 U.S.C. 717b. In order to carry out its statutory responsibility, FE requires those persons seeking to import or export natural gas to file an application and provide basic information on the scope and nature of the proposed import/export activity. Once an importer or exporter receives authorization from FE, they are required to submit monthly reports of all import and export transactions. Form FE–746R collects critical information on U.S. natural gas trade including: Name of importer/exporter; country of origin/destination; international point of entry/exit; name of supplier; volume; price; transporter; geographic market served; and duration of supply contract on a monthly basis. The data, published in *Natural Gas Imports and Exports,* are used to ensure compliance with the terms and conditions of the authorizations. In addition, the data are used to monitor North American gas trade, which, in turn, enables the Federal government to perform market and regulatory analyses; improve the capability of industry and the government to respond to any future energy-related supply problems; and keep the general public informed of international natural gas trade;

(4a) FE proposes to add the following reporting sections. These sections will serve only to clarify the reporting and will not add data elements to the reporting burden. The current forms authorization holders use to report their data does not properly align with the modes of transportation used, or the products being exported and imported. While there are new forms being added, these forms will be a direct substitute for the current forms for applicable authorization holders. These sections are for the collection and identification of new types of natural gas transactions related to:

(a) Exports/imports of compressed natural gas by vessel;

a. Current form does not cover compressed natural gas by vessel,

(b) Exports/imports of compressed natural gas by rail;

a. Current form does not cover compressed natural gas by rail,

(c) Exports/imports of compressed natural gas by waterborne transport;

a. Current form does not cover compressed natural gas by waterborne transport,

(d) Exports/imports of liquefied natural gas by rail;

a. Current form does not cover exports/imports by rail,

(e) Exports/imports of liquefied natural gas by waterborne transport;

a. Current form does not cover exports/imports by waterborne transport,

(f) Other exports and imports of natural gas by rail, truck, vessel, and waterborne transport;

a. Current form does not cover non-liquefied natural gas or pipeline gas exports/imports,

(g) Re-export of liquefied natural gas by vessel;

a. Current form does not cover re-export of liquefied natural gas

(h) Exports/Imports of liquefied natural gas by vessel in International Standards Organization (ISO) containers.

a. Current form also does not cover ISO containers

(5) *Annual Estimated Number of Respondents*: 371;

(6) *Annual Estimated Number of Total Responses*: 4,452;

(7) *Annual Estimated Number of Burden Hours*: 13,356;

(8) *Annual Estimated Reporting and Recordkeeping Cost Burden*: There are no additional costs associated with the surveys other than the burden hours. The information is maintained in the normal course of business. The cost of burden hours to the respondents is estimated to be $961,899 (13,356 burden hours times $72.02 per hour). Therefore, other than the cost of burden hours, FE estimates that there are no additional costs for generating, maintaining and providing the information.

Statutory Authority: Section 13(b) of the Federal Energy Administration Act of 1974, Public Law 93–275, codified at 15 U.S.C. 772(b) and section 3 of the Natural Gas Act of 1938, codified at 15 U.S.C. 717b.

Issued in Washington, DC, on May 4, 2016.

Nanda Srinivasan,

Director, Office of Survey Development and Statistical Integration, U.S. Energy Information Administration.

[FR Doc. 2016–10951 Filed 5–9–16; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP16–878–000.

Applicants: Texas Eastern Transmission, LP.

Description: Section 4(d) Rate Filing: Negotiated Rates—BP Energy Contract 911353 to be effective 5/1/2016.

Filed Date: 4/28/16.

Accession Number: 20160428–5073.

Comments Due: 5 p.m. ET 5/10/16.

Docket Numbers: RP16–879–000.

Applicants: Northern Natural Gas Company.

Description: Section 4(d) Rate Filing: 20160428 Winter PRA Fuel Rates to be effective 11/1/2016.

Filed Date: 4/28/16.

Accession Number: 20160428–5252.

Comments Due: 5 p.m. ET 5/10/16.

Docket Numbers: RP16–880–000.

Applicants: Equitrans, L.P.

Description: Section 4(d) Rate Filing: Negotiated Rate AGS Service Agreement—EQT Energy effective 5–1–2016 to be effective 5/1/2016.

Filed Date: 4/28/16.

Accession Number: 20160428–5295.

Comments Due: 5 p.m. ET 5/10/16.

Docket Numbers: RP16–881–000.

Applicants: El Paso Natural Gas Company, L.L.C.

Description: Section 4(d) Rate Filing: Negotiated Rate Agreement Update (APS May 2016) to be effective 5/1/2016.

Filed Date: 4/28/16.

Accession Number: 20160428–5296.

Comments Due: 5 p.m. ET 5/10/16.

Docket Numbers: RP16–882–000.

Applicants: Gulfstream Natural Gas System, L.L.C.

Description: Compliance filing 2016 GNGS TUP/SBA.

Filed Date: 4/29/16.

Accession Number: 20160429–5000.

Comments Due: 5 p.m. ET 5/11/16.

Docket Numbers: RP16–883–000.

Applicants: Southeast Supply Header, LLC.

Description: Section 4(d) Rate Filing: 2016 SESH TUP/SBA Annual Filing to be effective 6/1/2016.

Filed Date: 4/29/16.

Accession Number: 20160429–5001.

Comments Due: 5 p.m. ET 5/11/16.

Docket Numbers: RP16–884–000.

Applicants: Cheyenne Plains Gas Pipeline Company, L.

Description: Section 4(d) Rate Filing: FL&U to be effective June 1, 2016 to be effective 6/1/2016.

Filed Date: 4/29/16.

Accession Number: 20160429–5003.

Comments Due: 5 p.m. ET 5/11/16.

Docket Numbers: RP16–885–000.

Applicants: Wyoming Interstate Company, L.L.C.

Description: Section 4(d) Rate Filing: Fuel and L&U Rates to be effective 6/1/2016.

Filed Date: 4/29/16.

Accession Number: 20160429–5005.

Comments Due: 5 p.m. ET 5/11/16.

Docket Numbers: RP16–886–000.

Applicants: ANR Pipeline Company.

Description: Section 4(d) Rate Filing: Cashout Surcharge 2016 to be effective 6/1/2016.

Filed Date: 4/29/16.

Accession Number: 20160429–5011.

Comments Due: 5 p.m. ET 5/11/16.

Docket Numbers: RP16–887–000.

Applicants: ETC Tiger Pipeline, LLC.

Description: Section 4(d) Rate Filing: Fuel Filing on 4–29–16 to be effective 6/1/2016.

Filed Date: 4/29/16.

Accession Number: 20160429–5013.

Comments Due: 5 p.m. ET 5/11/16.

Docket Numbers: RP16–888–000.

Applicants: Fayetteville Express Pipeline LLC.

Description: Section 4(d) Rate Filing: Fuel Filing on 4–29–16 to be effective 6/1/2016.

Filed Date: 4/29/16.

Accession Number: 20160429–5014.

Comments Due: 5 p.m. ET 5/11/16.

Docket Numbers: RP16–889–000.

Applicants: Florida Gas Transmission Company, LLC.

Description: Section 4(d) Rate Filing: Reticulated Area Points to be effective 6/1/2016.

Filed Date: 4/29/16.

Accession Number: 20160429–5016.

Comments Due: 5 p.m. ET 5/11/16.

Docket Numbers: RP16–890–000.

Applicants: Gulf South Pipeline Company, LP.

Description: Section 4(d) Rate Filing: Cap Rel Neg Rate Agmt Filing (Oglethorpe 8482 to NJR 46096) to be effective 5/1/2016.

Filed Date: 4/29/16.

Accession Number: 20160429–5089.

Comments Due: 5 p.m. ET 5/11/16.

Docket Numbers: RP16–891–000.

Applicants: Texas Gas Transmission, LLC.

Description: Compliance filing Compliance Filing in Docket No. CP14–553–000 to submit Neg Rate Agmts to be effective 6/1/2016.

Filed Date: 4/29/16.

Accession Number: 20160429–5092.

Comments Due: 5 p.m. ET 5/11/16.

Docket Numbers: RP16–892–000.

Applicants: Gulf South Pipeline Company, LP.

Description: Section 4(d) Rate Filing: Cap Rel Neg Rate Agmt (FPL 41618 to Tenaska 46324) to be effective 5/1/2016.

Filed Date: 4/29/16.

Accession Number: 20160429–5093.

Comments Due: 5 p.m. ET 5/11/16.

Docket Numbers: RP16–893–000.

Applicants: Gulf South Pipeline Company, LP.

Description: Section 4(d) Rate Filing: Cap Rel Neg Rate Agmt (FPL 41618 to LaClede 46332) to be effective 5/1/2016.

Filed Date: 4/29/16.

Accession Number: 20160429–5097.

Comments Due: 5 p.m. ET 5/11/16.

Docket Numbers: RP16–894–000.

Applicants: Gulf South Pipeline Company, LP.

Description: Section 4(d) Rate Filing: Update to Pre-Effective Date Amendments to be effective 6/1/2016.

Filed Date: 4/29/16.

Accession Number: 20160429–5098.

Comments Due: 5 p.m. ET 5/11/16.

Docket Numbers: RP16–895–000.

Applicants: Natural Gas Pipeline Company of America.

Description: Section 4(d) Rate Filing: Occidental Energy Marketing to be effective 5/1/2016.

Filed Date: 4/29/16.

Accession Number: 20160429–5125.

Comments Due: 5 p.m. ET 5/11/16.

Docket Numbers: RP16–896–000.

Applicants: Natural Gas Pipeline Company of America.

Description: Section 4(d) Rate Filing: Macquarie Energy LLC to be effective 5/1/2016.
Filed Date: 4/29/16.
Accession Number: 20160429–5149.
Comments Due: 5 p.m. ET 5/11/16.

Docket Numbers: RP16–897–000.
Applicants: Natural Gas Pipeline Company of America.
Description: Section 4(d) Rate Filing: Tenaska to be effective 5/1/2016.
Filed Date: 4/29/16.
Accession Number: 20160429–5152.
Comments Due: 5 p.m. ET 5/11/16.

Docket Numbers: RP16–898–000.
Applicants: Midcontinent Express Pipeline LLC.
Description: Section 4(d) Rate Filing: Fuel Tracking Filing April 2016 to be effective 6/1/2016.
Filed Date: 4/29/16.
Accession Number: 20160429–5154.
Comments Due: 5 p.m. ET 5/11/16.

Docket Numbers: RP16–899–000.
Applicants: East Tennessee Natural Gas, LLC.
Description: Section 4(d) Rate Filing: OFO and Scheduling Revisions to be effective 6/1/2016.
Filed Date: 4/29/16.
Accession Number: 20160429–5158.
Comments Due: 5 p.m. ET 5/11/16.

Docket Numbers: RP16–900–000.
Applicants: Kinetica Deepwater Express, LLC.
Description: Section 4(d) Rate Filing: Kinetica Deepwater Express Tariff Name Change and Cleanup Filing to be effective 6/1/2016.
Filed Date: 4/29/16.
Accession Number: 20160429–5161.
Comments Due: 5 p.m. ET 5/11/16.

Docket Numbers: RP16–901–000.
Applicants: Gas Transmission Northwest LLC.
Description: Section 4(d) Rate Filing: Portland General Electric Negotiated Rate to be effective 5/1/2016.
Filed Date: 4/29/16.
Accession Number: 20160429–5165.
Comments Due: 5 p.m. ET 5/11/16.

Docket Numbers: RP16–902–000.
Applicants: Algonquin Gas Transmission, LLC.
Description: Section 4(d) Rate Filing: Negotiated Rates—Colonial Releases to BBPC 791520 & 791521 to be effective 5/1/2016.
Filed Date: 4/29/16.
Accession Number: 20160429–5167.
Comments Due: 5 p.m. ET 5/11/16.

Docket Numbers: RP16–903–000.
Applicants: Transcontinental Gas Pipe Line Company,
Description: Section 4(d) Rate Filing: Negotiated Rates—Cherokee AGL—Replacement Shippers—May 2016 to be effective 5/1/2016.
Filed Date: 4/29/16.
Accession Number: 20160429–5177.
Comments Due: 5 p.m. ET 5/11/16.

Docket Numbers: RP16–904–000.
Applicants: Algonquin Gas Transmission, LLC.
Description: Section 4(d) Rate Filing: Negotiated Rates—Baystate to BBPC 791489 to be effective 5/1/2016.
Filed Date: 4/29/16.
Accession Number: 20160429–5178.
Comments Due: 5 p.m. ET 5/11/16.

Docket Numbers: RP16–905–000.
Applicants: Algonquin Gas Transmission, LLC.
Description: Section 4(d) Rate Filing: Negotiated Rate Amendment—BP 510820 to be effective 5/1/2016.
Filed Date: 4/29/16.
Accession Number: 20160429–5285.
Comments Due: 5 p.m. ET 5/11/16.

Docket Numbers: RP16–906–000.
Applicants: Northern Natural Gas Company.
Description: Section 4(d) Rate Filing: 20160429 Negotiated Rate to be effective 5/1/2016.
Filed Date: 4/29/16.
Accession Number: 20160429–5314.
Comments Due: 5 p.m. ET 5/11/16.

Docket Numbers: RP16–907–000.
Applicants: Iroquois Gas Transmission System, L.P.
Description: Section 4(d) Rate Filing: 04/29/16 Negotiated Rates—Empire Generating Co, LLC (RTS) 7480–06 to be effective 5/1/2016.
Filed Date: 4/29/16.
Accession Number: 20160429–5318.
Comments Due: 5 p.m. ET 5/11/16.

Docket Numbers: RP16–908–000.
Applicants: Texas Eastern Transmission, LP.
Description: Section 4(d) Rate Filing: EPC JUNE 2016 FILING to be effective 6/1/2016.
Filed Date: 4/29/16.
Accession Number: 20160429–5320.
Comments Due: 5 p.m. ET 5/11/16.

Docket Numbers: RP16–909–000.
Applicants: Rockies Express Pipeline LLC.
Description: Section 4(d) Rate Filing: Neg Rate 2016–04–29 CP to be effective 5/1/2016.
Filed Date: 4/29/16.
Accession Number: 20160429–5407.
Comments Due: 5 p.m. ET 5/11/16.

Docket Numbers: RP16–910–000.
Applicants: Dominion Cove Point LNG, LP.
Description: Section 4(d) Rate Filing: DCP—St. Charles Transportation Project (CP15–22) to be effective 6/1/2016.
Filed Date: 4/29/16.
Accession Number: 20160429–5461.
Comments Due: 5 p.m. ET 5/11/16.

Docket Numbers: RP16–911–000.
Applicants: Alliance Pipeline L.P.
Description: Section 4(d) Rate Filing: May 1–31 2016 Service to be effective 5/1/2016.
Filed Date: 4/29/16.
Accession Number: 20160429–5470.
Comments Due: 5 p.m. ET 5/11/16.

Docket Numbers: RP16–913–000.
Applicants: Great Lakes Gas Transmission Limited Par.
Description: Great Lakes Gas Transmission's Revenue Cap and Revenue Sharing Mechanism True-Up Report.
Filed Date: 4/29/16.
Accession Number: 20160429–5515.
Comments Due: 5 p.m. ET 5/11/16.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

Filings in Existing Proceedings

Docket Numbers: RP15–65–000.
Applicants: Gulf South Pipeline Company, LP.
Description: Report Filing: Settlement Refund Report in Docket No. RP15–65–000.
Filed Date: 4/29/16.
Accession Number: 20160429–5110.
Comments Due: 5 p.m. ET 5/11/16.

Docket Numbers: RP16–137–007.
Applicants: Tallgrass Interstate Gas Transmission, L.
Description: Compliance filing Motion Filing for Rate Case to be effective 5/1/2016.
Filed Date: 4/28/16.
Accession Number: 20160428–5287.
Comments Due: 5 p.m. ET 5/10/16.

Docket Numbers: RP13–584–004.
Applicants: Columbia Gas Transmission, LLC.
Description: Compliance filing Revenue Sharing Report—2016.
Filed Date: 4/29/16.
Accession Number: 20160429–5245.
Comments Due: 5 p.m. ET 5/11/16.

Docket Numbers: RP16–501–003.
Applicants: High Point Gas Transmission, LLC.
Description: Compliance filing Compliance for NAESB Order Version 3 to be effective 4/1/2016.
Filed Date: 4/29/16.
Accession Number: 20160429–5192.
Comments Due: 5 p.m. ET 5/11/16.

Docket Numbers: RP16–532–002.
Applicants: Hardy Storage Company, LLC.

Description: Compliance filing Order 809 & NAESB 3.0 Errata Filing to be effective 4/1/2016.
Filed Date: 4/29/16.
Accession Number: 20160429–5466.
Comments Due: 5 p.m. ET 5/11/16.

Docket Numbers: RP16–696–001.
Applicants: Transcontinental Gas Pipe Line Company.
Description: Compliance filing Docket No. RP16–696–000 Compliance Filing—WSS Incremental Rates.
Filed Date: 4/29/16.
Accession Number: 20160429–5452.
Comments Due: 5 p.m. ET 5/11/16.

Docket Numbers: RP16–857–002.
Applicants: Eastern Shore Natural Gas Company.
Description: Compliance filing Amended Order On Compliance Order to be effective 4/1/2016.
Filed Date: 4/29/16.
Accession Number: 20160429–5469.
Comments Due: 5 p.m. ET 5/11/16.

Any person desiring to protest in any of the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: May 2, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–10870 Filed 5–9–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP16–912–000.
Applicants: Rockies Express Pipeline LLC.
Description: § 4(d) Rate Filing: Neg Rate 2015–05–02 Encana 2 Ks to be effective 5/1/2016.
Filed Date: 5/2/16.
Accession Number: 20160502–5030.
Comments Due: 5 p.m. ET 5/16/16.

Docket Numbers: RP16–914–000.
Applicants: Northern Border Pipeline Company.
Description: Northern Border Pipeline Company's Operational Purchases and Sales of Gas Report under RP16–914.
Filed Date: 4/29/16.
Accession Number: 20160429–5531.
Comments Due: 5 p.m. ET 5/11/16.

Docket Numbers: RP16–915–000.
Applicants: Gulf South Pipeline Company, LP.
Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmts (PH 41455 to Texla 46343) to be effective 5/1/2016.
Filed Date: 5/2/16.
Accession Number: 20160502–5108.
Comments Due: 5 p.m. ET 5/16/16.

Docket Numbers: RP16–916–000.
Applicants: Gulf South Pipeline Company, LP.
Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmts (Atlanta 8438 to various eff 5–1–16) to be effective 5/1/2016.
Filed Date: 5/2/16.
Accession Number: 20160502–5109.
Comments Due: 5 p.m. ET 5/16/16.

Docket Numbers: RP16–917–000.
Applicants: Gulf South Pipeline Company, LP.
Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmts (Encana 37663 to BP 46375) to be effective 5/1/2016.
Filed Date: 5/2/16.
Accession Number: 20160502–5110.
Comments Due: 5 p.m. ET 5/16/16.

Docket Numbers: RP16–918–000.
Applicants: Iroquois Gas Transmission System, L.P.
Description: § 4(d) Rate Filing: 05/02/16. Negotiated Rates—Conoco Phillips Company (RTS) 3015–05 to be effective 5/1/2016.
Filed Date: 5/2/16.
Accession Number: 20160502–5134.
Comments Due: 5 p.m. ET 5/16/16.

Docket Numbers: RP16–919–000.
Applicants: Equitrans, L.P.
Description: Compliance filing Notice Regarding Non-Jurisdictional Gathering Facilities (M–63).
Filed Date: 5/2/16.
Accession Number: 20160502–5197.
Comments Due: 5 p.m. ET 5/16/16.

Docket Numbers: RP16–920–000.
Applicants: Great Lakes Gas Transmission Limited Par.
Description: Great Lakes Gas Transmission's Operational Purchases and Sales of Gas Report.
Filed Date: 4/29/16.
Accession Number: 20160429–5551.
Comments Due: 5 p.m. ET 5/11/16.

Docket Numbers: RP16–921–000.
Applicants: ANR Storage Company.
Description: ANR Storage Company's Operational Purchases and Sales Report.
Filed Date: 4/29/16.
Accession Number: 20160429–5552.
Comments Due: 5 p.m. ET 5/11/16.

Docket Numbers: RP16–922–000.
Applicants: Bison Pipeline LLC.
Description: Bison Pipeline LLC.'s Operational Purchases and Sales Report.
Filed Date: 4/29/16.
Accession Number: 20160429–5554.
Comments Due: 5 p.m. ET 5/11/16.

Docket Numbers: RP16–923–000.
Applicants: Blue Lake Gas Storage Company.
Description: Blue Lake Gas Storage Company Operational Purchases and Sales of Gas Report.
Filed Date: 4/29/16.
Accession Number: 20160429–5555.
Comments Due: 5 p.m. ET 5/11/16.

Docket Numbers: RP16–924–000.
Applicants: ANR Pipeline Company.
Description: ANR Pipeline Company's Operational Purchases and Sales Report.
Filed Date: 4/29/16.
Accession Number: 20160429–5559.
Comments Due: 5 p.m. ET 5/11/16.

Docket Numbers: RP16–925–000.
Applicants: Rockies Express Pipeline LLC.
Description: § 4(d) Rate Filing: Neg Rate 2016–05–02 Perm Partial CR ARM to be effective 5/1/2016.
Filed Date: 5/2/16.
Accession Number: 20160502–5305.
Comments Due: 5 p.m. ET 5/16/16.

Docket Numbers: RP16–926–000.
Applicants: Dominion Transmission, Inc.
Description: § 4(d) Rate Filing: DTI—May 2, 2016 Nonconforming Service Agreement to be effective 6/1/2016.
Filed Date: 5/2/16.
Accession Number: 20160502–5344.
Comments Due: 5 p.m. ET 5/16/16.

Docket Numbers: RP16–927–000.
Applicants: Equitrans, L.P.
Description: § 4(d) Rate Filing: Negotiated Capacity Release Agreements—5/01/2016 to be effective 5/1/2016.
Filed Date: 5/2/16.
Accession Number: 20160502–5350.
Comments Due: 5 p.m. ET 5/16/16.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and § 385.214) on or before 5:00 p.m. Eastern time on the specified comment date.

Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: May 3, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–10871 Filed 5–9–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM98–1–000]

Records Governing Off-the-Record Communications; Public Notice

This constitutes notice, in accordance with 18 CFR 385.2201(b), of the receipt of prohibited and exempt off-the-record communications.

Order No. 607 (64 FR 51222, September 22, 1999) requires Commission decisional employees, who make or receive a prohibited or exempt off-the-record communication relevant to the merits of a contested proceeding, to deliver to the Secretary of the Commission, a copy of the communication, if written, or a summary of the substance of any oral communication.

Prohibited communications are included in a public, non-decisional file associated with, but not a part of, the decisional record of the proceeding. Unless the Commission determines that the prohibited communication and any responses thereto should become a part of the decisional record, the prohibited off-the-record communication will not be considered by the Commission in reaching its decision. Parties to a proceeding may seek the opportunity to respond to any facts or contentions made in a prohibited off-the-record communication, and may request that the Commission place the prohibited communication and responses thereto in the decisional record. The Commission will grant such a request only when it determines that fairness so requires. Any person identified below as having made a prohibited off-the-record communication shall serve the document on all parties listed on the official service list for the applicable proceeding in accordance with Rule 2010, 18 CFR 385.2010.

Exempt off-the-record communications are included in the decisional record of the proceeding, unless the communication was with a cooperating agency as described by 40 CFR 1501.6, made under 18 CFR 385.2201(e)(1)(v).

The following is a list of off-the-record communications recently received by the Secretary of the Commission. The communications listed are grouped by docket numbers in ascending order. These filings are available for electronic review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the eLibrary link. Enter the docket number, excluding the last three digits, in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202)502–8659.

Prohibited:

Docket No.	File date	Presenter or requester
1. CP16–21–000	4–18–2016	Ada Peters.
2. CP16–21–000	4–18–2016	Mass Mailing[1].
3. CP16–21–000	4–19–2016	Cathy Richardson.
4. CP16–21–000	4–19–2016	Mark S. Peters.
5. CP14–96–000	4–19–2016	Paul M. Blanch.
6. CP16–21–000	4–21–2016	Luceese Purcede.
7. CP16–21–000	4–21–2016	Darrell Scott.
8. CP13–483–000 CP13–492–000	4–21–2016	International Union of Operating Engineers.
9. CP16–21–000	4–22–2016	Mass Mailing[2].
10. CP14–103–000 CP15–115–000	4–25–2016	Ruth A. Carter.
11. CP16–21–000	4–26–2016	Louise Purcell.
12. CP16–21–000	4–29–2016	Mass Mailing[3].
13. CP15–514–000	4–29–2016	Ohio Gas Association.
14. CP15–514–000	4–29–2016	The Ohio Manufacturers' Association.

[1] 4 letters have been sent to FERC Commissioners and staff under this docket number.

[2] 2 letters have been sent to FERC Commissioners and staff under this docket number.

[3] 2 letters have been sent to FERC Commissioners and staff under this docket number.

Exempt:

.	Docket No.	File date
1. CP13–483–000 CP13–492–000	4–18–2016	U.S. Congress Members[4].
2. CP13–483–000 CP13–492–000	4–18–2016	U.S. Congress Members[5].
3. P–13755–000 P–13757–000 P–13761–000 P–13768–000	4–18–2016	U.S. House Representatives[6].
4. EL16–33–000 EL16–34–000	4–20–2016	U.S. Senator Joe Manchin III.
5. P–14677–001	4–20–2016	FERC Staff[7].

.	Docket No.	File date
6. P–13102–003	4–21–2016	FERC Staff[8].
7. EL16–33–000 EL16–34–000	4–22–2016	FERC Staff[9].
8. CP16–21–000	4–25–2016	U.S. Senator Kelly A. Ayotte.
9. EL16–33–000 EL16–34–000	4–26–2016	FERC Staff[10].
10. EL16–33–000 EL16–34–000	4–27–2016	FERC Staff[11].
11. EL16–33–000 EL16–34–000	4–27–2016	FERC Staff[12].

[4] Senator Jerry Moran and House Representative Kevin Yoder.

[5] Senators John Barrasso, M.D., Cory Gardner, Michael F. Bennet, Mike Lee, Michael B. Enzi, and Orrin G. Hatch. House Representatives Cynthia Lummis, Scott R. Tipton, Doug Lamborn, Mike Coffman, Jason Chaffetz, Mia Love, Rob Bishop, Chris Stewart, and Ken Buck.

[6] Mike Doyle and Keith Rothfus.

[7] Telephone Record from April 19, 2016 call with John Gangemi from ERM.

[8] Telephone Record from April 19, 2016 call with Nick Josten from GeoSense.

[9] Telephone Record from April 20, 2016 call with Senator Joe Manchin.

[10] Telephone Record from April 21, 2016 call with Senator Joe Manchin.

[11] Telephone Record from April 20, 2016 call with Senator Joe Manchin.

[12] Telephone Record from April 20, 2016 call with Senator Joe Manchin.

Dated: May 3, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–10869 Filed 5–9–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Number: PR16–50–000.
Applicants: Pacific Gas and Electric Company.
Description: Tariff filing per 284.123(e)/.224: Revisions to Statement of Operating Conditions to be effective 4/1/2016; Filing Type: 770.
Filed Date: 4/26/2016.
Accession Number: 201604265162.
Comments/Protests Due: 5 p.m. ET 5/17/16.

Docket Numbers: RP16–876–000.
Applicants: Rockies Express Pipeline LLC.
Description: Section 4(d) Rate Filing: Neg Rate 2016–04–27 Encana, CP to be effective 5/1/2016.
Filed Date: 4/27/16.
Accession Number: 20160427–5150.
Comments Due: 5 p.m. ET 5/9/16.

Docket Numbers: RP16–877–000.
Applicants: ANR Storage Company.
Description: Petition to Amend Settlement and Motion for Shortened Answer and Expedited Action under RP16–877.
Filed Date: 4/26/16.
Accession Number: 20160426–5333.
Comments Due: 5 p.m. ET 5/3/16.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified date(s). Protests may be considered, but intervention is necessary to become a party to the proceeding.

Filings in Existing Proceedings

Docket Numbers: RP16–501–002.
Applicants: High Point Gas Transmission, LLC.
Description: Compliance filing Compliance with NAESB Order to be effective 4/1/2016.
Filed Date: 4/27/16.
Accession Number: 20160427–5143.
Comments Due: 5 p.m. ET 5/9/16.

Docket Numbers: RP16–857–001.
Applicants: Eastern Shore Natural Gas Company.
Description: Compliance filing Amended Order On Compliance Order to be effective 4/1/2016.
Filed Date: 4/27/16.
Accession Number: 20160427–5267.
Comments Due: 5 p.m. ET 5/9/16.

Any person desiring to protest in any of the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: April 28, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–10904 Filed 5–9–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG16–90–000.
Applicants: Beacon Solar 1, LLC.
Description: Notice of Self-Certification of Exempt Wholesale Generator (EWG) Status of Beacon Solar 1, LLC.
Filed Date: 5/3/16.
Accession Number: 20160503–5081.
Comments Due: 5 p.m. ET 5/24/16.

Docket Numbers: EG16–91–000.
Applicants: Beacon Solar 3, LLC.
Description: Notice of Self-Certification of Exempt Wholesale Generator (EWG) of Beacon Solar 3, LLC.
Filed Date: 5/3/16.
Accession Number: 20160503–5082.
Comments Due: 5 p.m. ET 5/24/16.

Docket Numbers: EG16–92–000.
Applicants: Beacon Solar 4, LLC.
Description: Notice of Self-Certification of Exempt Wholesale Generator (EWG) Status of Beacon Solar 4, LLC.
Filed Date: 5/3/16.
Accession Number: 20160503–5083.
Comments Due: 5 p.m. ET 5/24/16.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–2964–011.
Applicants: Selkirk Cogen Partners, L.P.
Description: Notice of Non-Material Change in Status of Selkirk Cogen Partners, L.P.
Filed Date: 4/29/16.
Accession Number: 20160429–5579.
Comments Due: 5 p.m. ET 5/20/16.

Docket Numbers: ER13–1942–003.
Applicants: New York Independent System Operator, Inc.
Description: Compliance filing: Compliance filing to remove rejected text and insert missing text into the OATT to be effective. 1/15/2013
Filed Date: 5/2/16.
Accession Number: 20160502–5297.
Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER14–1578–006.
Applicants: PacifiCorp.
Description: Load Aggregation Point Disaggregation Study of PacifiCorp.
Filed Date: 4/29/16.
Accession Number: 20160429–5604.
Comments Due: 5 p.m. ET 5/20/16.

Docket Numbers: ER15–114–002.
Applicants: Alterna Springerville LLC.
Description: Notice of Non-Material Change in Status of Alterna Springerville LLC.
Filed Date: 4/29/16.
Accession Number: 20160429–5582.
Comments Due: 5 p.m. ET 5/20/16.

Docket Numbers: ER16–846–001.
Applicants: Southwest Power Pool, Inc.
Description: Compliance filing: 3165 Substitute Otter Tail Power Company NITSA and NOA—Compliance Filing to be effective 1/1/2016.
Filed Date: 5/2/16.
Accession Number: 20160502–5346.
Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–853–001; ER16–855–001; ER16–856–001; ER16–857–001; ER16–858–001; ER16–860–001; ER16–861–001.
Applicants: Enterprise Solar, LLC, Escalante Solar I, LLC, Escalante Solar II, LLC, Escalante Solar III, LLC, Granite Mountain Solar East, LLC, Granite Mountain Solar West, LLC, Iron Springs Solar, LLC.
Description: Notice of in Change in Status of the Dominion Companies, et al.
Filed Date: 4/29/16.
Accession Number: 20160429–5586.
Comments Due: 5 p.m. ET 5/20/16.

Docket Numbers: ER16–862–001.
Applicants: Southwest Power Pool, Inc.
Description: Compliance filing: 3126R1 Substitute WAPA NITSA and NOA—Compliance Filing to be effective 1/1/2016.
Filed Date: 5/2/16.
Accession Number: 20160502–5271.
Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–863–001.
Applicants: Southwest Power Pool, Inc.
Description: Compliance filing: 3125R1 Substitute Basin Electric Power Cooperative NITSA—Compliance Filing to be effective 1/1/2016.
Filed Date: 5/2/16.
Accession Number: 20160502–5289.
Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1302–001.
Applicants: Southern California Edison Company.
Description: Tariff Amendment: Resubmit Amended LGIA Coso Finance Partners to be effective 1/1/2016.
Filed Date: 5/3/16.
Accession Number: 20160503–5063.
Comments Due: 5 p.m. ET 5/24/16.

Docket Numbers: ER16–1603–000.
Applicants: San Diego Gas & Electric Company.
Description: § 205(d) Rate Filing: SDG&E TO4 Formula Depreciation Rate Change 2016 to be effective 1/1/2017.
Filed Date: 5/2/16.
Accession Number: 20160502–5286.
Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1604–000.
Applicants: San Diego Gas & Electric Company.
Description: § 205(d) Rate Filing: SDG&E TO4 Formula Depreciation Rate Change 2016 to be effective 1/1/2017.
Filed Date: 5/2/16.
Accession Number: 20160502–5354.
Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1607–000.
Applicants: Alabama Power Company, Georgia Power Company.
Description: Notice of Termination of the Transmission Facilities Agreement Between Alabama Power Company and Georgia Power Company.
Filed Date: 4/29/16.
Accession Number: 20160429–5584.
Comments Due: 5 p.m. ET 5/20/16.

Docket Numbers: ER16–1608–000.
Applicants: Mississippi Power Company, Gulf Power Company.
Description: Notice of Termination of the Transmission Facilities Agreement Between Mississippi Power Company and Gulf Power Company.
Filed Date: 4/29/16.
Accession Number: 20160429–5587.
Comments Due: 5 p.m. ET 5/20/16.

Docket Numbers: ER16–1609–000.
Applicants: ID SOLAR 1, LLC.
Description: Baseline eTariff Filing: Baseline New to be effective 5/4/2016.
Filed Date: 5/3/16.
Accession Number: 20160503–5068.
Comments Due: 5 p.m. ET 5/24/16.

Docket Numbers: ER16–1610–000.
Applicants: V3 Commodities Group, LLC.
Description: Baseline eTariff Filing: Baseline New to be effective 5/4/2016.
Filed Date: 5/3/16.
Accession Number: 20160503–5078.
Comments Due: 5 p.m. ET 5/24/16.

Docket Numbers: ER16–1611–000.
Applicants: PJM Interconnection, L.L.C.
Description: Tariff Cancellation: Notice of Cancellation of WMPA SA No. 3254, Queue No. W4–065 due to Breach to be effective 5/3/2016.
Filed Date: 5/3/16.
Accession Number: 20160503–5096.
Comments Due: 5 p.m. ET 5/24/16.

Docket Numbers: ER16–1612–000.
Applicants: Georgia Power Company.
Description: Compliance filing: Compliance Filing to March 4, 2016 Letter Order issued in Docket No. ER16–586 to be effective 1/1/2015.
Filed Date: 5/3/16.
Accession Number: 20160503–5097.
Comments Due: 5 p.m. ET 5/24/16.

Docket Numbers: ER16–1613–000.
Applicants: California Power Exchange Corporation.
Description: § 205(d) Rate Filing: Rate Filing for Rate Period 29 to be effective 7/1/2016.
Filed Date: 5/3/16.
Accession Number: 20160503–5098.
Comments Due: 5 p.m. ET 5/24/16.

Docket Numbers: ER16–1614–000.
Applicants: Louisiana Generating LLC.
Description: Request of Louisiana Generating LLC to recover costs associated with acting as a Local Balancing Authority under MISO Tariff.
Filed Date: 5/2/16.
Accession Number: 20160502–5400.
Comments Due: 5 p.m. ET 5/23/16.

Docket Numbers: ER16–1615–000.
Applicants: PJM Interconnection, L.L.C.
Description: Tariff Cancellation: Notice of Cancellation WMPA SA No. 3442, Queue No. X1–114 due to Breach to be effective 5/3/2016.
Filed Date: 5/3/16.
Accession Number: 20160503–5101.
Comments Due: 5 p.m. ET 5/24/16.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES16–31–000.
Applicants: Delmarva Power & Light Company, Potomac Electric Power Company.
Description: Application for Authorization to Issue Securities of PHI

Service Company on behalf of the Applicants.

Filed Date: 4/29/16.

Accession Number: 20160429–5565.

Comments Due: 5 p.m. ET 5/20/16.

Docket Numbers: ES16–32–000.

Applicants: Transource West Virginia, LLC.

Description: Application Under Section 204 of the Federal Power Act for Authorization to Issue Securities of Transource West Virginia, LLC.

Filed Date: 4/29/16.

Accession Number: 20160429–5598.

Comments Due: 5 p.m. ET 5/20/16.

Docket Numbers: ES16–33–000.

Applicants: Transource Missouri, LLC.

Description: Application Under Section 204 of the Federal Power Act for Authorization to Issue Securities of Transource Missouri, LLC.

Filed Date: 4/29/16.

Accession Number: 20160429–5601.

Comments Due: 5 p.m. ET 5/20/16.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: May 3, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–10866 Filed 5–9–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC16–110–000.

Applicants: Fortis Inc., Finn Investment Pte. Ltd., FortisUS Inc., ITC Investment Holdings Inc., Element Acquisition Sub Inc., Enterprise Holdings Pte. Ltd., ITC Holdings Corp.

Description: Joint Application for Authorization for Merger and Disposition of Jurisdictional Transmission Facilities by Fortis Inc., Finn Investment Pte, Ltd., and ITC Holdings Corp., et. al.

Filed Date: 4/28/16.

Accession Number: 20160428–5468.

Comments Due: 5 p.m. ET 5/19/16.

Docket Numbers: EC16–111–000.

Applicants: Comanche Solar PV, LLC.

Description: Application for Authorization under Section 203 of the Federal Power Act and Request for Waivers, Confidential Treatment, Expedited Action and Shortened Comment Period, Comanche Solar PV, LLC.

Filed Date: 4/28/16.

Accession Number: 20160428–5475.

Comments Due: 5 p.m. ET 5/19/16.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER15–1308–003.

Applicants: Kingfisher Wind, LLC.

Description: Notice of Non-Material Change in Status of Kingfisher Wind, LLC.

Filed Date: 4/28/16.

Accession Number: 20160428–5470.

Comments Due: 5 p.m. ET 5/19/16.

Docket Numbers: ER16–1533–000.

Applicants: PacifiCorp.

Description: § 205(d) Rate Filing: BPA Non-Conforming PTP Agreements to be effective 4/1/2016.

Filed Date: 4/29/16.

Accession Number: 20160429–5262.

Comments Due: 5 p.m. ET 5/20/16.

Docket Numbers: ER16–1534–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: § 205(d) Rate Filing: 2016–04–29_Non-Transmission Owner Cost Recovery Filing to be effective 7/1/2016.

Filed Date: 4/29/16.

Accession Number: 20160429–5283.

Comments Due: 5 p.m. ET 5/20/16.

Docket Numbers: ER16–1535–000.

Applicants: Tampa Electric Company.

Description: § 205(d) Rate Filing: Emergency Interchange Service Schedule A&B–2016 (Bundled) to be effective 5/1/2016.

Filed Date: 4/29/16.

Accession Number: 20160429–5309.

Comments Due: 5 p.m. ET 5/20/16.

Docket Numbers: ER16–1536–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 3190 Basin Electric and MidAmerican Energy Attachment AO to be effective 4/1/2016.

Filed Date: 4/29/16.

Accession Number: 20160429–5321.

Comments Due: 5 p.m. ET 5/20/16.

Docket Numbers: ER16–1537–000.

Applicants: New England Power Pool Participants Committee.

Description: § 205(d) Rate Filing: May 2016 Membership Filing to be effective 4/1/2016.

Filed Date: 4/29/16.

Accession Number: 20160429–5337.

Comments Due: 5 p.m. ET 5/20/16.

Docket Numbers: ER16–1538–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: § 205(d) Rate Filing: 2016–04–29_SA 2823 Termination MidAmerican-Ida Grove Wind E&P (J411) to be effective 4/22/2016.

Filed Date: 4/29/16.

Accession Number: 20160429–5338.

Comments Due: 5 p.m. ET 5/20/16.

Docket Numbers: ER16–1539–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: § 205(d) Rate Filing: 2016–04–29_SA 2822 Termination MidAmerican-Highland Wind E&P (J285) to be effective 4/22/2016.

Filed Date: 4/29/16.

Accession Number: 20160429–5343.

Comments Due: 5 p.m. ET 5/20/16.

Docket Numbers: ER16–1540–000.

Applicants: PacifiCorp.

Description: § 205(d) Rate Filing: BPA Non-Conforming PTP Agreements to be effective 4/1/2016.

Filed Date: 4/29/16.

Accession Number: 20160429–5369.

Comments Due: 5 p.m. ET 5/20/16.

Docket Numbers: ER16–1541–000.

Applicants: California Independent System Operator Corporation.

Description: § 205(d) Rate Filing: 2015–04–29 Rate Schedule No. 83, Idaho Power EIM Implementation Agreement to be effective 7/1/2016.

Filed Date: 4/29/16.

Accession Number: 20160429–5370.

Comments Due: 5 p.m. ET 5/20/16.

Docket Numbers: ER16–1542–000.

Applicants: Public Service Company of Colorado.

Description: § 205(d) Rate Filing: PSCo FSV Const Agrmt NOC–286 to be effective 6/29/2016.

Filed Date: 4/29/16.

Accession Number: 20160429–5373.

Comments Due: 5 p.m. ET 5/20/16.

Docket Numbers: ER16–1543–000.

Applicants: Louisville Gas and Electric Company.

Description: § 205(d) Rate Filing: Schedule 1 Amend Rate Update Date to be effective 5/1/2016.

Filed Date: 4/29/16.

Accession Number: 20160429–5379.

Comments Due: 5 p.m. ET 5/20/16.

Docket Numbers: ER16–1544–000.

Applicants: Southwest Power Pool, Inc.

Description: Compliance filing: Compliance Filing Revising Westar Energy's Formula Rate Template to be effective 8/20/2014.

Filed Date: 4/29/16.

Accession Number: 20160429–5390.

Comments Due: 5 p.m. ET 5/20/16.

Docket Numbers: ER16–1545–000.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Cancellation: Notice of Cancellation of ISA No. 3045 and ICSA No. 3046, Queue No. Q65 to be effective 6/27/2016.

Filed Date: 4/29/16.

Accession Number: 20160429–5424.

Comments Due: 5 p.m. ET 5/20/16.

Docket Numbers: ER16–1546–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: Arkansas Electric Cooperative Corporation Formula Rate to be effective 7/1/2016.

Filed Date: 4/29/16.

Accession Number: 20160429–5439.

Comments Due: 5 p.m. ET 5/20/16.

Docket Numbers: ER16–1547–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Amendment to ISAs 1867 & 4128, Queues NQ#117 & NQ#124, per Assignment to be effective 6/1/2015.

Filed Date: 4/29/16.

Accession Number: 20160429–5446.

Comments Due: 5 p.m. ET 5/20/16.

Docket Numbers: ER16–1548–000.

Applicants: California Independent System Operator Corporation.

Description: § 205(d) Rate Filing: 2016–04–29 Mesquite Solar 3 LGIA to be effective 6/1/2016.

Filed Date: 4/29/16.

Accession Number: 20160429–5456.

Comments Due: 5 p.m. ET 5/20/16.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: April 29, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–10865 Filed 5–9–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL16–60–000]

Vineland Municipal Electric Utility v. Atlantic City Electric Company; Notice of Complaint

Take notice that on April 26, 2016, pursuant to sections 205, 206, 306, and 309 of the Federal Power Act (FPA)[1] and Rules 206 and 217 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure,[2] Vineland Municipal Electric Utility (Vineland or Complainant) filed a formal complaint against Atlantic City Electric Company (ACE or Respondent). Vineland is seeking an order granting full and immediate refunds of all amounts paid in violation of the Interconnection Agreement and PJM Open Access Transmission Tariff (PJM OATT). Vineland is alleging ACE's decision to, without prior notice or approval from Vineland, apply a Reconciliation Factor to Vineland's five coincident hourly metered loads for the purpose of calculating Vineland's capacity obligation, is in violation of the Interconnection Agreement and the PJM OATT, as more fully explained in the complaint.

Complainant certifies that copies of the Complaint were served on the contacts for the Respondents.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protests must be served on the Complainants.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on May 16, 2016.

Dated: April 28, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–10906 Filed 5–9–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Commission Staff Attendance

The Federal Energy Regulatory Commission hereby gives notice that members of the Commission's staff may attend the following meetings related to the transmission planning activities of the PJM Interconnection, L.L.C. (PJM):

PJM Planning Committee

May 12, 2016, 9:30 a.m.–12:00 p.m. (EST)

PJM Transmission Expansion Advisory Committee

May 12, 2016, 11:00 a.m.–3:00 p.m. (EST)

The above-referenced meetings will be held at: PJM Conference and Training Center, PJM Interconnection, 2750 Monroe Boulevard, Audubon, PA 19403.

The above-referenced meetings are open to stakeholders.

Further information may be found at *www.pjm.com.*

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[1] 16 U.S.C. 824d, 824e, 825e, and 825h (2016).

[2] 18 CFR 385.206, 385.217 (2016).

The discussions at the meetings described above may address matters at issue in the following proceedings:

Docket No. ER16–453, *PJM Interconnection, L.L.C. and Northeast Transmission Development, LLC*
Docket No. ER16–736, *PJM Interconnection, L.L.C.*
Docket No. ER14–972, *PJM Interconnection, L.L.C.*
Docket No. ER14–1485, *PJM Interconnection, L.L.C.*
Docket Nos. ER13–1944, *et al., PJM Interconnection, L.L.C., et al.*
Docket No. ER15–1344, *PJM Interconnection, L.L.C.*
Docket No. ER15–1387, *PJM Interconnection, L.L.C. and Potomac Electric Power Company*
Docket No. ER15–2562, *PJM Interconnection, L.L.C.*
Docket No. ER15–2563, *PJM Interconnection, L.L.C.*
Docket No. EL15–18, *Consolidated Edison Company of New York, Inc.* v. *PJM Interconnection, L.L.C.*
Docket No. EL15–41, *Essential Power Rock Springs, LLC, et. al.* v. *PJM Interconnection, L.L.C.*
Docket No. ER15–2114, *PJM Interconnection, L.L.C. and Transource West Virginia, LLC*
Docket No. EL15–79, *TransSource, LLC* v. *PJM Interconnection, L.L.C.*
Docket No. EL15–95, *Delaware Public Service Commission, et. al.,* v. *PJM Interconnection, L.L.C., et. al.*
Docket No. EL15–67, *Linden VFT, LLC* v. *PJM Interconnection, L.L.C.*
Docket No. EL05–121, *PJM Interconnection, L.L.C.*
Docket No. ER13–198, *PJM Interconnection, L.L.C.*
Docket No. ER16–1335, *PJM Interconnection, L.L.C.*
Docket No. ER16–1232, *PJM Interconnection, L.L.C.*

For more information, contact the following:

Jonathan Fernandez; Office of Energy Market Regulation; Federal Energy Regulatory Commission; (202) 502–6604; *Jonathan.Fernandez@ferc.gov.*

Alina Halay; Office of Energy Market Regulation; Federal Energy Regulatory Commission; (202) 502–6474; *Alina.Halay@ferc.gov.*

Dated: May 4, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–10969 Filed 5–9–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM16–12–000; Docket No. RM15–21–000]

Review of Generator Interconnection Agreements and Procedures—American Wind Energy Association; Supplemental Notice of Technical Conference

As announced in the Notice of Technical Conference issued on March 29, 2016 [1] and the Supplemental Notice of Technical Conference issued on April 13, 2016 [2] in the above-captioned proceedings, Federal Energy Regulatory Commission (Commission) staff will hold a technical conference on May 13, 2016 to discuss select issues related to a petition for rulemaking submitted by the American Wind Energy Association (Docket No. RM15–21–000).[3] In addition, the conference will explore other generator interconnection issues, including interconnection of electric storage resources. The conference will be held from 9:00 a.m. to 4:55 p.m. (EDT) (a time change from prior Notice of Technical Conference) in the Commission Meeting Room at Commission headquarters, 888 First Street NE., Washington, DC 20426. Members of the Commission may attend the conference, which will also be open for the public to attend. Advance registration is not required, but is encouraged. Attendees may register at the following Web page: *https://www.ferc.gov/whats-new/registration/05-13-16-form.asp.*

An agenda with a list of selected speakers is attached and will be available in the Commission Calendar of Events at *http://www.ferc.gov.*

Discussions at the conference may involve issues raised in proceedings that are currently pending before the Commission. These proceedings include, but are not limited to:

Northern Indiana Public Service Company, Docket No. EL13–88–000;

E.ON Climate & Renewables North America LLC, Pioneer Trail Wind Farm, LLC, Settlers Trail Wind Farm, LLC v. Northern Indiana Public Service Company, Docket No. EL14–66–002;

Internal MISO Generators v. Midcontinent Independent System Operator, Inc., Docket No. EL15–99–000 and EL16–12;

Midcontinent Independent System Operator, Inc., Docket No. ER16–675–000;

California Independent System Operator Corporation, Docket No. ER16–693–000;

ISO New England, Inc., Docket No. ER16–946–000;

California Independent System Operator Corporation, Docket No. ER16–1085–000;

Midcontinent Independent System Operator, Inc., Docket No. ER16–1120–000;

Midcontinent Independent System Operator, Inc., Docket No. ER16–1211–000;

Southwest Power Pool, Inc., Docket No. ER16–1350–000; and

Southern California Edison Company, Docket No. ER16–1459–000.

The conference will be transcribed and webcast. A link to the webcast of this event will be available in the Commission Calendar of Events at *http://www.ferc.gov.* Transcripts of the technical conference will be available for a fee from Ace-Reporting (202–347–3700). The Capitol Connection provides technical support for the webcasts and offers the option of listening to the conferences via phone-bridge for a fee. For additional information, visit *www.CapitolConnection.org* or call (703) 993–3100.

Commission conferences are accessible under section 508 of the Rehabilitation Act of 1973. For accessibility accommodations, please send an email to *accessibility@ferc.gov* or call toll free (866) 208–3372 (voice) or (202) 502–8659 (TTY), or send a FAX to (202) 208–2106 with the required accommodations.

For more information about the technical conference, please contact Tony Dobbins (*Tony.Dobbins@ferc.gov;* 202–502–6630) or Adam Pan (*Adam.Pan@ferc.gov;* 202–502–6023). For information related to logistics, please contact Sarah McKinley (*Sarah.Mckinley@ferc.gov;* 202–502–8368).

Dated: May 4, 2016.

Kimberly D. Bose,

Secretary.

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[1] Review of Generator Interconnection Agreements and Procedures, Docket No. RM16–12–000 and American Wind Energy Association, Docket No. RM15–21–000 (Mar. 29, 2016) (Notice of Technical Conference).

[2] Review of Generator Interconnection Agreements and Procedures, Docket No. RM16–12–000 and American Wind Energy Association, Docket No. RM15–21–000 (Apr. 13, 2016) (Supplemental Notice of Technical Conference).

[3] The comments filed in Docket No. RM15–21–000 will be incorporated into Docket No. RM16–12–000.

DEPARTMENT OF ENERGY · FEDERAL ENERGY REGULATORY COMMISSION

Review of Generator Interconnection Agreements and Procedures Technical Conference

Docket Nos. RM16–12–000 and RM15–21–000

May 13, 2016, Washington, DC

9:00 a.m.–9:20 a.m. Welcome and Commission Staff Opening Remarks

9:20 a.m.–10:20 a.m. The Current State of Generator Interconnection Queues

Panelists should be prepared to discuss the following topics:

1. How well generator interconnection queues are working, the metrics that are used to evaluate queue performance, and whether there are clear areas in which improvement is needed.

2. Whether projects in the queue contributing most significantly to queue backlogs are geographically dispersed or concentrated. Whether there are queue solutions that might adequately account for the geographic characteristics of projects contributing to queue congestion.

3. Queue management practices and whether there are best practices that should be incorporated across regions.

4. The extent to which regions have pursued changes to the generator interconnection process that could be implemented without requiring tariff changes, as noted by the Commission in the 2008 order on interconnection queue practices.[1]

5. The primary considerations that should be taken into account when developing solutions for each region's individual interconnection queue issues.

Panelists:

- **Tim Aliff, Director of Reliability Planning, Midcontinent Independent System Operator, Inc.**
- **David Gabbard, Director, Electric Generation Interconnection, Pacific Gas and Electric Company**
- **Dean Gosselin, Vice President of Business Management Transmission Services, NextEra Energy Resources LLC**
- **Alan McBride, Director, Transmission Strategy and Services, ISO New England, Inc.**
- **Steven Naumann, Vice President, Exelon Corporation**
- **Rick Vail, Vice President, Transmission, PacifiCorp**

10:20 a.m.–10:30 a.m.: Break

10:30 a.m.–12:00 p.m.: Transparency and Timing in the Generator Interconnection Study Process

Panelists should be prepared to discuss the following topics:

1. The length of time it takes to complete the interconnection process, causes of variances in receiving study results, causes of variations in length of time in the queue, and how delays (and their causes) are reported to interconnection customers.

2. How study costs are determined, how consistent these costs are between markets and regions, whether (and how) interconnection customers are made aware of study costs in advance of requesting interconnection service.

3. The information (models, assumptions, cost estimates, etc.) to which interconnection customers currently have access and the stage in the interconnection process when such access is provided (pre-request, study stage, etc.). Whether additional information (historical and/or projected curtailment or pricing information, etc.) should be available to interconnection customers to assist them in planning projects, and the challenges and/or barriers to providing this information.

4. How the capacity factor used for variable generation modeling is determined (in general terms) and shared with interconnection customers.

5. The triggers for restudy, how they are determined, and whether they are stated in the tariff. The possible effect that limiting the number of restudies would have on reliability or cost estimates, allocations, or assignments.

Panelists:

- **David Angell, Customer Operations Planning Manager, Idaho Power**
- **Jennifer Ayers-Brasher, Director, Transmission & Market Analysis, E.ON Climate & Renewables NA**
- **Joshua Bohach, Senior Development Manager, EDP Renewables North America**
- **David Egan, Manager—Interconnection Projects, PJM Interconnection, L.L.C.**
- **Charles Hendrix, Manager, Generation Interconnection Studies, Southwest Power Pool, Inc.**
- **Randall Oye, Transmission Access Analyst, Xcel Energy**
- **Stephen Rutty, Director of Grid Assets, California Independent System Operator, Inc.**
- **Kris Zadlo, Senior Vice President, Invenergy LLC**

12:00 p.m.–1:00pm Break for Lunch

1:00 p.m.–2:10 p.m. Certainty in Cost Estimates and Construction Time

Panelists should be prepared to discuss the following topics:

1. The manner in which disputes regarding interconnection configurations or direct assignment and network upgrade costs are typically resolved and how such disputes could be avoided. The frequency of such disputes.

2. When cost and construction schedule estimates are provided to interconnection customers and the accuracy of these estimates compared to actual results. Whether early cost estimates are sufficient to allow customers to make decisions whether to move forward with a project. The process changes necessary to provide more accurate estimates earlier to interconnection customers.

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[1] *Interconnection Queueing Practices*, 122 FERC ¶ 61,252, at P 10 (2008). As guidance in this order, the Commission stated that reforms made without tariff changes could include: increasing the staff available to work on interconnection studies; adopting more efficient modeling for feasibility studies or system impact studies; and performing a single system impact study for a cluster of interconnection requests.

3. The factors that affect accuracy of cost and schedule estimates and how estimate variances can be reduced.

4. How other queued facilities that may impact an interconnection customer's request are identified and when interconnection customers are made aware of such facilities (*e.g.*, a lower-queued project being informed that the withdrawal of a specific higher-queued project may affect it). The challenges of identifying those facilities that may impact an interconnection request.

Panelists:

- **Tim Aliff, Director of Reliability Planning, Midcontinent Independent System Operator, Inc.**
- **Dean Gosselin, Vice President of Business Management Transmission Services, NextEra Energy Resources LLC**
- **Paul Kelly, Director, Federal Regulatory Policy, Northern Indiana Public Service Company**
- **Omar Martino, Director, Transmission, EDF Renewable Energy**
- **Alan McBride, Director, Transmission Strategy and Services, ISO New England, Inc.**
- **Stephen Rutty, Director of Grid Assets, California Independent System Operator, Inc.**
- **Rick Vail, Vice President, Transmission, PacifiCorp**

2:10 p.m.–2:20 p.m. Break

2:20 p.m.–3:30 p.m. Other Interconnection Queue Coordination and Management Issues

Panelists should be prepared to discuss the following topics:

1. Coordinating interconnection requests with affected systems[2] and the challenges associated with affected system coordination and areas for improvement.

2. The types of changes to a project that should be allowed without changing the project's position in the queue, *i.e.*, determining an appropriate threshold for modifications to a project before it should lose its place in the queue.

3. How to manage the effects of project withdrawals from the interconnection queue and possible best practices to keep the queue moving despite project withdrawal. The appropriate balance between attempts to prevent speculative projects from entering the queue and the recognition that the study process is designed to iteratively provide information that project developers will use to decide whether to proceed or withdraw (possibly causing restudies).

4. How transmission providers, transmission owners, and interconnection customers coordinate during the interconnection process, and possible areas for improvement.

5. Technologies, tools, or administrative processes that could improve the accuracy of cost and time estimates, reduce the processing time, or increase the efficiency of the interconnection queue process.

Panelists:

- **Tim Aliff, Director of Reliability Planning, Midcontinent Independent System Operator, Inc.**
- **David Angell, Customer Operations Planning Manager, Idaho Power**
- **Jennifer Ayers-Brasher, Director, Transmission & Market Analysis, E.ON Climate & Renewables NA**
- **Daniel Barr, Principal Engineer, ITC Holdings**
- **Charles Hendrix, Manager, Generation Interconnection Studies, Southwest Power Pool, Inc.**
- **Paul Kelly, Director, Federal Regulatory Policy, Northern Indiana Public Service Company**
- **Omar Martino, Director, Transmission, EDF Renewable Energy**
- **Steven Naumann, Vice President, Exelon Corporation**

3:30 p.m.–4:45 p.m. Interconnection of Electric Storage Resources

Panelists should be prepared to discuss the following topics:

1. Whether existing small and large *pro forma* interconnection agreements and procedures are sufficient to accommodate the interconnection of electric storage resources.

2. Modeling of electric storage resources for interconnection studies, including potential means for interconnection studies to better reflect the intended operation of electric storage devices.

3. Interconnection of combined storage and generation facilities, including (i) the appropriate level of interconnection service for the combined facility; (ii) the operational understanding, telemetry, and metering of the combined facility; and (iii) the appropriate interconnection process for adding storage to an existing generation facility.

4. Potential processes to facilitate the interconnection of electric storage resources.

5. Interconnection of distribution-level and aggregated electric storage resources that participate in the RTO and ISO markets.

Panelists:

- **David Egan, Manager—Interconnection Projects, PJM Interconnection, L.L.C.**
- **Mason Emnett, Senior Attorney, NextEra Energy, Inc.**
- **John Fernandes, Director, Policy & Market Development, RES Americas**
- **David Gabbard, Director, Electric Generation Interconnection, Pacific Gas and Electric Company**
- **Alan McBride, Director, Transmission Strategy and Services, ISO New England, Inc.**
- **Stephen Rutty, Director of Grid Assets, California Independent System Operator, Inc.**

4:45 p.m.–4:55 p.m. Closing Remarks

[FR Doc. 2016–10967 Filed 5–9–16; 8:45 am]

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[2] As defined in the *pro forma* LGIA and *pro forma* LGIP, Affected System refers to an electric system other than the transmission provider's transmission system that may be affected by the proposed interconnection. Order No. 2003–A, FERC Stats. & Regs. ¶ 31,160 at App. 6 (Standard Large Generator Interconnection Agreement), art. 1, *order on reh'g,* Order No. 2003–B, FERC Stats. & Regs. ¶ 31,171 (2004), *order on reh'g,* Order No. 2003–C, FERC Stats. & Regs. ¶ 31,190 (2005), *aff'd sub nom. Nat'l Ass'n of Regulatory Util. Comm'rs* v. *FERC,* 475 F.3d 1277 (D.C. Cir. 2007), *cert. denied,* 552 U.S. 1230 (2008).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. EL16–62–000]

Golden Spread Electric Cooperative, Inc.; Notice of Petition for Declaratory Order

Take notice that on April 28, 2016, pursuant to section 292.402 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 292.402 (2015), Golden Spread Electric Cooperative, Inc., (Golden Spread), on behalf of itself and its sixteen (16) distribution cooperative members-owners (collectively, Participating Members),[1] filed a petition for a

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[1] The Participating Members include: Bailey County Electric Cooperative Association; Big Country Electric Cooperative, Inc.; Coleman County Electric Cooperative, Inc.; Concho Valley Electric Cooperative, Inc.; Deaf Smith Electric Cooperative, Inc.; Greenbelt Electric Cooperative, Inc.; Lamb County Electric Cooperative, Inc.; Lighthouse Electric Cooperative, Inc.; Lyntegar Electric Cooperative, Inc.; North Plains Electric Cooperative,

Continued

declaratory order requesting a partial waiver of certain obligations imposed on Golden Spread and the Participating Members under sections 292.303(a) and 292.303(b)[2] of the Commission's regulations implementing section 210 of the Public Utility Regulatory Policies Act of 1978, all as more fully explained in the petition.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Petitioner.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern time on May 31, 2016.

Dated: April 28, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–10907 Filed 5–9–16; 8:45 am]

BILLING CODE 6717–01–P

Inc.; Rita Blanca Electric Cooperative, Inc.; South Plains Electric Cooperative, Inc.; Southwest Texas Electric Cooperative, Inc.; Swisher Electric Cooperative, Inc.; Taylor Electric Cooperative, Inc.; and Tri-County Electric Cooperative, Inc.

[2] 18 CFR 292.303(a) and 292.303(b).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER16–1509–000]

New Wave Energy Corp; Supplemental Notice That Initial Market-Based Rate Filing Includes Request For Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of New Wave Energy Corp's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is May 18, 2016.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: April 28, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–10908 Filed 5–9–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC16–108–000.
Applicants: Tenaska Alabama II Partners, L.P.
Description: Tenaska Alabama II Partners, L.P. Application for Approval Under Section 203 of the Federal Power Act and Request for Expedited Action.
Filed Date: 4/27/16.
Accession Number: 20160427–5340.
Comments Due: 5 p.m. ET 5/18/16.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER16–1051–001.
Applicants: Graphic Packaging International Inc.
Description: Tariff Amendment: Supplement to Application for Order Accepting Initial Market-Based Rate Tariff to be effective 3/1/2016.
Filed Date: 4/28/16.
Accession Number: 20160428–5085.
Comments Due: 5 p.m. ET 5/19/16.

Docket Numbers: ER16–1152–001.
Applicants: Jericho Rise Wind Farm LLC.
Description: Tariff Amendment: Revised Proposed MBR Tariff to be effective 5/14/2016.
Filed Date: 4/27/16.
Accession Number: 20160427–5244.
Comments Due: 5 p.m. ET 5/18/16.

Docket Numbers: ER16–1154–001.
Applicants: Parrey, LLC.
Description: Tariff Amendment: Supplement to App. for MBR Authorization in Response to Informal Staff Request to be effective 4/1/2016.
Filed Date: 4/27/16.
Accession Number: 20160427–5243.
Comments Due: 5 p.m. ET 5/18/16.

Docket Numbers: ER16–1509–000.
Applicants: New Wave Energy Corp.
Description: Baseline eTariff Filing: New Wave Energy Corporation to be effective 6/27/2016.
Filed Date: 4/27/16.
Accession Number: 20160427–5291.

Comments Due: 5 p.m. ET 5/18/16.

Docket Numbers: ER16–1510–000.

Applicants: PPL Electric Utilities Corporation, PJM Interconnection, L.L.C.

Description: Section 205(d) Rate Filing: PPL Electric submits revised Interconnection Agreement No. 746 to be effective 6/1/2016.

Filed Date: 4/28/16.

Accession Number: 20160428–5055.

Comments Due: 5 p.m. ET 5/19/16.

Docket Numbers: ER16–1511–000.

Applicants: PJM Interconnection, L.L.C.

Description: Section 205(d) Rate Filing: 1st Quarter 2016 Updates to OA and RAA Member Lists to be effective 3/31/2016.

Filed Date: 4/28/16.

Accession Number: 20160428–5200.

Comments Due: 5 p.m. ET 5/19/16.

Take notice that the Commission received the following PURPA 210(m)(3) filings:

Docket Numbers: QM16–3–000.

Applicants: Golden Spread Electric Cooperative, Inc.

Description: Application Pursuant to Section 292.310(A) for Authorization to Terminate Mandatory Purchase Obligation in ERCOT of Golden Spread Electric Cooperative, Inc.

Filed Date: 4/27/16.

Accession Number: 20160427–5337.

Comments Due: 5 p.m. ET 5/25/16.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: April 28, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–10902 Filed 5–9–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IN12–17–000]

Total Gas & Power North America, Aaron Hall and Therese Tran f/k/a/ Nguyen; Notice of Designation of Commission Staff as Non-Decisional

With respect to an order issued by the Commission on April 28, 2016 in the above-captioned docket,[1] with the exceptions noted below, the staff of the Office of Enforcement are designated as non-decisional in deliberations by the Commission in this docket. Accordingly, pursuant to 18 CFR 385.2202 (2015), they will not serve as advisors to the Commission or take part in the Commission's review of any offer of settlement. Likewise, as non-decisional staff, pursuant to 18 CFR 385.2201 (2015), they are prohibited from communicating with advisory staff concerning any deliberations in this docket.

Exceptions to this designation as non-decisional are:

Demetra Anas
John Carnes
Taylor Martin
Lisa Owings
Eric Primosch
Felice Richter
Emily Scruggs
Derek Shiau
Andrew Tamayo
David Zlotnick

Dated: April 28, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–10909 Filed 5–9–16; 8:45 am]

BILLING CODE 6717–01–P

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[1] *Total Gas & Power North America, Aaron Hall and Therese Tran f/k/a Nguyen,* 155 FERC ¶ 61,105 (2016).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL16–56–000]

Consumer Energy Company; Notice of Institution of Section 206 Proceeding and Refund Effective Date

On April 28, 2016, the Commission issued an order in Docket No. EL16–56–000, pursuant to section 206 of the Federal Power Act (FPA), 16 U.S.C. 824e (2012), instituting an investigation into the justness and reasonableness of Consumer Energy Company's proposed rate reduction. *Consumer Energy Company,* 155 FERC ¶ 61, 104 (2016).

The refund effective date in Docket No. EL16–56–000, established pursuant to section 206(b) of the FPA, will be the date of publication of this notice in the **Federal Register**.

Dated: April 28, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–10905 Filed 5–9–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice Of Filings # 2

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–3117–005.

Applicants: Lea Power Partners, LLC.

Description: Supplement to December 16, 2015 Triennial Market Power Analysis Filing for Southwest Power Pool region of Lea Power Partners, LLC.

Filed Date: 4/20/16.

Accession Number: 20160420–5197.

Comments Due: 5 p.m. ET 5/11/16.

Docket Numbers: ER13–2409–006; *ER11–4501–011; ER12–2448–010; ER15–2615–001; ER15–2620–001; ER14–2858–005; ER12–979–010; ER11–4499–010; ER11–4498–010.*

Applicants: Buffalo Dunes Wind Project, LLC, Caney River Wind Project, LLC, Chisholm View Wind Project, LLC, Goodwell Wind Project, LLC, Little Elk Wind Project, LLC, Origin Wind Energy, LLC, Rocky Ridge Wind Project, LLC, Smoky Hills Wind Farm, LLC, Smoky Hills Wind Project II, LLC.

Description: Supplement to December 18, 2015 Updated Market Power Analysis and Order No. 697 Compliance Filing of Buffalo Dunes Wind Project, LLC, et al.

Filed Date: 4/15/16.

Accession Number: 20160415–5339.

Comments Due: 5 p.m. ET 5/6/16.

Docket Numbers: ER16–1616–000.

Applicants: Puget Sound Energy, Inc.

Description: § 205(d) Rate Filing: Orcas NITSA S.A. No 792 and Orcas NOA S.A No 793 to be effective 5/1/2016.

Filed Date: 5/3/16.

Accession Number: 20160503–5124.

Comments Due: 5 p.m. ET 5/24/16.

Docket Numbers: ER16–1617–000.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Cancellation: Notice of Cancellation of WMPA SA No. 3445, Queue No. X1–073 due to Breach to be effective 5/3/2016.

Filed Date: 5/3/16.
Accession Number: 20160503–5142.
Comments Due: 5 p.m. ET 5/24/16.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: May 3, 2016.

Nathaniel J. Davis, Sr.,
Deputy Secretary.

[FR Doc. 2016–10867 Filed 5–9–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Technical Conference

	Docket No.
Alabama Power Company	ER10–2881–014
Southern Power Company	ER10–2882–014
Mississippi Power Company	ER10–2883–014
Georgia Power Company	ER10–2884–014
Gulf Power Company	ER10–2885–014
Oleander Power Project, Limited Partnership	ER10–2641–014
Southern Company—Florida LLC	ER10–2663–014
Southern Turner Cimarron I, LLC	ER10–2886–014
Spectrum Nevada Solar, LLC	ER13–1101–009
Campo Verde Solar, LLC	ER13–1541–008
Macho Springs Solar, LLC	ER14–787–002
	EL15–39–000

Take notice that the Federal Energy Regulatory Commission (Commission) will convene a staff-led technical conference in the above-referenced proceedings on May 23, 2016. The conference will begin at 9:00 a.m. (Eastern Time). The conference will be held in the Commission Meeting Room at the headquarters of the Commission, 888 First Street NE., Washington, DC 20426. The technical conference may be attended by one or more Commissioners.

The purpose of this conference is to discuss select issues related to the market-based rate authorization of the above-captioned entities. The conference will explore potential ways to improve the energy auction currently serving as tailored mitigation or whether there are possible alternative forms of mitigation. Attached is an agenda for the conference. This technical conference is not intended to address other issues relevant to the above-captioned entities' updated market power analysis.[1]

If attendees would like to file written responses to the questions in the attached agenda prior to the conference to facilitate the discussion, the Commission invites such written responses, with a deadline of May 18, 2016. The Commission will accept comments following the conference, with a deadline of June 6, 2016.[2]

There is no fee for attendance. In-person attendees should allow time to pass through building security procedures before the start time of the technical conference. Pre-registration is encouraged though not required. Attendees may register in advance at the following Web page: *https://www.ferc.gov/whats-new/registration/05-23-16-form.asp.*

The conference will be transcribed and webcast. Transcripts will be available immediately for a fee from Ace Reporting (202–347–3700). A link to the webcast of this event will be available in the Commission Calendar of Events at *www.ferc.gov.* The Capitol Connection provides technical support for the webcasts and offers the option of listening to the conferences via phone-bridge for a fee. For additional information, visit *www.CapitolConnection.org* or call (703) 993–3100.

Commission conferences are accessible under section 508 of the Rehabilitation Act of 1973. For accessibility accommodations please send an email to *accessibility@ferc.gov* or call toll free 1–866–208–3372 (voice) or 202–208–8659 (TTY), or send a fax to 202–208–2106 with the required accommodations.

For more information about this technical conference, please contact Lauren Campbell at *Lauren.Campbell@ferc.gov* or (202) 502–6642. For information related to logistics, please contact Sarah McKinley at *Sarah.Mckinley@ferc.gov* or (202) 502–8368.

Dated: May 4, 2016.

Kimberly D. Bose,
Secretary.

[FR Doc. 2016–10968 Filed 5–9–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER16–1489–000]

North Star Gas Company LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of North Star Gas Company LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

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[1] Other issues will be addressed in a future Commission order.

[2] The written responses and comments should be filed in the above-captioned dockets.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is May 23, 2016.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: May 3, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–10868 Filed 5–9–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC16–109–000.

Applicants: Nevada Power Company.

Description: Application of Nevada Power Company under Section 203 of the Federal Power Act.

Filed Date: 4/27/16.

Accession Number: 20160427–5354.

Comments Due: 5 p.m. ET 5/18/16.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER16–1513–000.

Applicants: PJM Interconnection, L.L.C., Monongahela Power Company.

Description: Section 205(d) Rate Filing: Monongahela Power submits revisions to OATT Att H–11A and Revised SA No. 3513 to be effective 2/1/2016.

Filed Date: 4/28/16.

Accession Number: 20160428–5225.

Comments Due: 5 p.m. ET 5/19/16.

Docket Numbers: ER16–1514–000.

Applicants: PJM Interconnection, L.L.C., Monongahela Power Company.

Description: Section 205(d) Rate Filing: Monongahela Power submits revisions to OATT Att H–11A and Revised SA No. 3513 to be effective 2/1/2016.

Filed Date: 4/28/16.

Accession Number: 20160428–5226.

Comments Due: 5 p.m. ET 5/19/16.

Docket Numbers: ER16–1515–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Request for Waiver of Midcontinent Independent System Operator, Inc.

Filed Date: 4/27/16.

Accession Number: 20160427–5348.

Comments Due: 5 p.m. ET 5/18/16.

Docket Numbers: ER16–1516–000.

Applicants: MidAmerican Energy Company.

Description: Section 205(d) Rate Filing: Interconnection Agr—Muscatine and ITC Midwest—Concurrence to be effective 6/6/2016.

Filed Date: 4/28/16.

Accession Number: 20160428–5294.

Comments Due: 5 p.m. ET 5/19/16.

Docket Numbers: ER16–1517–000.

Applicants: PJM Interconnection, L.L.C.

Description: Section 205(d) Rate Filing: Amendment to WMPA SA No. 3330, Queue No. X1–095 to be effective 7/2/2014.

Filed Date: 4/28/16.

Accession Number: 20160428–5310.

Comments Due: 5 p.m. ET 5/19/16.

Docket Numbers: ER16–1518–000.

Applicants: California Independent System Operator Corporation.

Description: Section 205(d) Rate Filing: 2016–04–28 EIM Year One Enhancements—Phase 2 to be effective 10/1/2016.

Filed Date: 4/28/16.

Accession Number: 20160428–5314.

Comments Due: 5 p.m. ET 5/19/16.

Docket Numbers: ER16–1519–000.

Applicants: PJM Interconnection, L.L.C.

Description: Section 205(d) Rate Filing: Service Agreement Nos. 4436, Queue Position T126, and 4437, Queue Position T127 to be effective 3/29/2016.

Filed Date: 4/28/16.

Accession Number: 20160428–5333.

Comments Due: 5 p.m. ET 5/19/16.

Docket Numbers: ER16–1520–000.

Applicants: PJM Interconnection, L.L.C.

Description: Section 205(d) Rate Filing: Revisions to OATT, OA & RAA to correct, clarify and clean-up various provisions to be effective 6/27/2016.

Filed Date: 4/28/16.

Accession Number: 20160428–5338.

Comments Due: 5 p.m. ET 5/19/16.

Docket Numbers: ER16–1521–000.

Applicants: PacifiCorp.

Description: Section 205(d) Rate Filing: WAPA Revised Spence/Thermopolis Agreements to be effective 6/28/2016.

Filed Date: 4/28/16.

Accession Number: 20160428–5345.

Comments Due: 5 p.m. ET 5/19/16.

Docket Numbers: ER16–1522–000.

Applicants: PacifiCorp.

Description: Tariff Cancellation: Termination of BPA General Transfer Agreement (East) to be effective 6/30/2016.

Filed Date: 4/28/16.

Accession Number: 20160428–5347.

Comments Due: 5 p.m. ET 5/19/16.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: April 28, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–10903 Filed 5–9–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER16–829–001.
Applicants: Southwest Power Pool, Inc.
Description: Tariff Amendment: Deficiency Response in ER16–829—Bylaws Section 8.4 Revisions to be effective 3/1/2016.
Filed Date: 4/28/16.
Accession Number: 20160428–5361.
Comments Due: 5 p.m. ET 5/19/16.

Docket Numbers: ER16–1498–001.
Applicants: South Carolina Electric & Gas Company.
Description: Tariff Amendment: Amendment of Pending Tariff Filing to be effective 5/15/2016.
Filed Date: 4/29/16.
Accession Number: 20160429–5069.
Comments Due: 5 p.m. ET 5/9/16.

Docket Numbers: ER16–1523–000.
Applicants: Southwest Power Pool, Inc.
Description: Section 205(d) Rate Filing: Revisions to Attachment L to Address Network Load Outside of the SPP Footprint to be effective 7/1/2016.
Filed Date: 4/28/16.
Accession Number: 20160428–5350.
Comments Due: 5 p.m. ET 5/19/16.

Docket Numbers: ER16–1524–000.
Applicants: PacifiCorp.
Description: Tariff Cancellation: Termination of BPA SIEA to be effective 6/30/2016.
Filed Date: 4/28/16.
Accession Number: 20160428–5353.
Comments Due: 5 p.m. ET 5/19/16.

Docket Numbers: ER16–1525–000.
Applicants: Pacific Gas and Electric Company.
Description: Section 205(d) Rate Filing: 7th Amendment to Extend the PGE–SVP Interconnection Agreement to be effective 6/30/2016.
Filed Date: 4/28/16.
Accession Number: 20160428–5362.
Comments Due: 5 p.m. ET 5/19/16.

Docket Numbers: ER16–1526–000.
Applicants: Southern California Edison Company.
Description: Section 205(d) Rate Filing: GIA and Distribution Service Agreement Commerce Refuse to Energy Authority to be effective 1/1/2017.
Filed Date: 4/29/16.
Accession Number: 20160429–5004.
Comments Due: 5 p.m. ET 5/20/16.

Docket Numbers: ER16–1527–000.
Applicants: Duke Energy Florida, LLC.
Description: Section 205(d) Rate Filing: DEF IA Annual Cost Factor Update (2016) to be effective 5/1/2016.
Filed Date: 4/29/16.
Accession Number: 20160429–5012.
Comments Due: 5 p.m. ET 5/20/16.

Docket Numbers: ER16–1528–000.
Applicants: Entergy Arkansas, Inc., Entergy Louisiana, LLC, Entergy Mississippi, Inc., Entergy Texas, Inc., Entergy New Orleans, Inc.
Description: Application of Entergy Services, Inc., on behalf of the Entergy Operating Companies for 2015 Transmission Formula Rate for Post-Retirement Benefits Other than Pensions.
Filed Date: 4/28/16.
Accession Number: 20160428–5406.
Comments Due: 5 p.m. ET 5/19/16.

Docket Numbers: ER16–1529–000.
Applicants: PJM Interconnection, L.L.C.
Description: Tariff Cancellation: Notice of Cancellation of WMPA SA No. 3285, Queue No. X1–082 due to Breach to be effective 4/28/2016.
Filed Date: 4/29/16.
Accession Number: 20160429–5151.
Comments Due: 5 p.m. ET 5/20/16.

Docket Numbers: ER16–1530–000.
Applicants: BIF III Holtwood LLC.
Description: Initial rate filing: Reactive Supply and Voltage Control Filing to be effective 6/1/2016.
Filed Date: 4/29/16.
Accession Number: 20160429–5164.
Comments Due: 5 p.m. ET 5/20/16.

Docket Numbers: ER16–1531–000.
Applicants: PJM Interconnection, L.L.C.
Description: Tariff Cancellation: Notice of Cancellation of WMPA SA No. 3457, Queue No. X3–082 due to Breach to be effective 4/28/2016.
Filed Date: 4/29/16.
Accession Number: 20160429–5242.
Comments Due: 5 p.m. ET 5/20/16.

Docket Numbers: ER16–1532–000.
Applicants: PJM Interconnection, L.L.C.
Description: Tariff Cancellation: Notice of Cancellation of WMPA SA No. 3458, Queue No. X3–083 due to Breach to be effective 4/28/2016.
Filed Date: 4/29/16.
Accession Number: 20160429–5246.
Comments Due: 5 p.m. ET 5/20/16.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: April 29, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–10864 Filed 5–9–16; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2015–0272; FRL–9946–23–OAR]

Protection of Stratospheric Ozone: Notice of Revocation and Voluntary Withdrawals of Programs From EPA's Section 608 Technician Certifying Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of revocations and voluntary withdrawals.

SUMMARY: EPA is removing programs that were revoked and those that submitted voluntary withdrawals from its list of Section 608 Technician Certification Programs approved to provide the technician certification exam. EPA's list is available at: *http://www.epa.gov/section608/section-608-technician-certification-programs.*

DATES: On February 1, 2016, authorization to provide the technician certification exam and to issue certification cards was revoked for each program in the Table below: Revoked Technician Certification Programs. Technicians that were already certified by these programs will remain certified, in accordance with 40 CFR 82.161(a).

FOR FURTHER INFORMATION CONTACT: Robert Burchard, Stratospheric Protection Division, Office of Atmospheric Programs (6205T), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number (202) 343–9126; fax number: (202) 343–2338; email address: *burchard.robert@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

How can I get copies of this document and other related information?

Docket. EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2015–0272. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the Air Docket, EPA/DC, WJC West Building, Room 3334, 1301 Constitution Avenue NW., Washington DC. This Docket Facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (202) 566–1742.

Electronic Access. You may access this **Federal Register** document electronically from the Government Printing Office under the "**Federal Register**" listings at the FDSys Web site (*http://www.gpo.gov/fdsys/browse/collection.action?collectionCode=FR*).

II. Revocations and Voluntary Withdrawals

In accordance with the standards for certifying programs established in appendix D of 40 CFR part 82, subpart F, technician certifying programs must submit an activity report to EPA on a biannual basis (such that EPA receives the report by every January 30 and June 30) that provides certain information about the certification tests administered. The programs in the Table below have repeatedly failed to submit activity reports.

The regulations at 40 CFR 82.161 establish criteria and procedures for such programs to become approved technician certification programs that can provide the certifications that are required for technicians under Section 608. As provided in 40 CFR 82.161(e), "[i]f at any time an approved program violates any of the above requirements," which reference the standards in appendix D that are cited in 82.161(c), "the Administrator reserves the right to revoke approval in accordance with Section 82.169." Today's notice announces the final revocation of the approval of the programs in the Table below.

These programs were sent certified letters explaining that EPA had not received required activity reports and listing which reports were missing. In the letters, the programs were offered the opportunity to come into compliance by submitting missing reports.[1] The Agency received no replies. In a **Federal Register** notice published December 2, 2015 (80 FR 75456), the programs in the table below were given thirty days from the date of publication of that notice to submit their missing reports. The notice announced that failure to submit these reports so that they were received by January 4, 2016 would result in an automatic suspension of the program's approval to offer the technician certification exam and of its approval to issue Section 608 technician certification cards. The notice also announced that automatic program revocation would occur on February 1, 2016 for each of those certifying organizations that were so notified of impending suspension and revocation and that failed to provide missing reports, unless the organization requested a hearing in accordance with the regulations published at 40 CFR 82.169 before that date. Since the Agency did not receive any reports from those certifying organizations by January 4, 2016, or requests for a hearing by February 1, 2016, the approval to certify technicians is revoked for all the programs listed in the following table:

TABLE—REVOKED TECHNICIAN CERTIFICATION PROGRAMS

No.	Technician certification program	Year of most recent activity report
1	ACI Environmental Safety Training Institute	2009.
2	California Career Center	No record of a submitted report.
3	Delaware County Community College	2011.
4	Delaware Skills Center Building Maintenance	2013.
5	Delaware Technical & Community College	2009.
6	Educational Services	2012.
7	HVAC/R Training, Inc	2010.
8	InSolution	No record of a submitted report.
9	Niagara County Community College	2010.
10	Nugent Associates	2011.
11	San Diego City College	2010.
12	Southern Technical College	2012.
13	Unified Industries, Inc	No record of a submitted report.
14	Vatterott College	2011.

Accordingly, we have updated the list of approved Section 608 Technician Certification Programs mentioned above by removing these programs from the list.

Additionally, as discussed in the December 2, 2015 Notice, the following 608 Technician Certification Programs voluntarily withdrew their certification and have been removed from the Agency's list of approved Section 608 Technician Certification Programs: Air-Conditioning & Refrigeration Institute (ARI); CDTA, Inc; and Motorcoach Training Specialist. Three programs—NASA; Kellogg Community College; and WyoTech—had prior to the December 2, 2015 Notice also submitted requests for voluntary withdrawal but were inadvertently omitted from that Notice. Consistent with those requests, these programs have also been removed from the Agency's list of approved Section 608 Technician Certification Programs.

Technicians that were already certified by all of these programs remain certified, in accordance with 40 CFR 82.161(a). Requests for replacement cards should be sent to: *spdcomments@epa.gov.*

Drusilla Hufford, Director,

Stratospheric Protection Division.

[FR Doc. 2016–10987 Filed 5–9–16; 8:45 am]

BILLING CODE 6560–50–P

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[1] Some of these programs also received notice in these letters of impending suspensions and revocations, but as some of these letters were returned to us unopened, we chose to provide a second notice in the **Federal Register**. 80 FR 75456.

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2015–0022; FRL–9945–50]

Pesticide Product Registrations; Receipt of Applications for New Uses

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received applications to register new uses for pesticide products containing currently registered active ingredients. Pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is hereby providing notice of receipt and opportunity to comment on these applications.

DATES: Comments must be received on or before June 9, 2016.

ADDRESSES: Submit your comments, identified by the Docket Identification (ID) Number and the File Symbol or EPA Registration Number of interest as shown in the body of this document, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.* Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Steve Knizer, Antimicrobials Division (AD) (7510P), main telephone number: (703) 305–7090, email address: *ADFRNotices@epa.gov;* Robert McNally, Biopesticides and Pollution Prevention Division (BPPD) (7511P), main telephone number: (703) 305–7090, email address: *BPPDFRNotices@epa.gov;* or Susan Lewis, Registration Division (RD) (7505P), main telephone number: (703) 305–7090, email address: *RDFRNotices@epa.gov.* The mailing address for each contact person is: Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001. As part of the mailing address, include the contact person's name, division, and mail code. The division to contact is listed at the end of each application summary.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT** for the division listed at the end of the application summary of interest.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html.*

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low-income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, EPA seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticides discussed in this document, compared to the general population.

II. Registration Applications

EPA has received applications to register new uses for pesticide products containing currently registered active ingredients. Pursuant to the provisions of FIFRA section 3(c)(4) (7 U.S.C. 136a(c)(4)), EPA is hereby providing notice of receipt and opportunity to comment on these applications. Notice of receipt of these applications does not imply a decision by EPA on these applications. For actions being evaluated under EPA's public participation process for registration actions, there will be an additional opportunity for public comment on the proposed decisions. Please see EPA's public participation Web site for additional information on this process *https://www.epa.gov/pesticide-registration/public-participation-process-registration-actions.* EPA received the following applications to register new uses for pesticide products containing currently registered active ingredients:

1. *EPA Registration Numbers and File Symbol:* 100–762, 100–763, and 81880–ET. *Docket ID Number:* EPA–HQ–OPP–2016–0218. *Applicants:* Syngenta Crop Protection, LLC, 410 Swing Rd., P.O. Box 18300, Greensboro, NC 27419–8300; and Canyon Group, LLC, 370 S. Main St., Yuma, AZ 85364. *Active Ingredient:* Prosulfuron. *Product Type:* Herbicide. *Proposed Uses:* Technical and end-use products intended for use in or on cereal grains group (crop group 15); forage, fodder, and straw of cereal grains group (crop group 16); and rice. *Contact:* RD.

2. *EPA Registration Number:* 100–1571. *Docket ID Number:* EPA–HQ–OPP–2016–0049. *Applicant:* Syngenta Crop Protection, LLC, 410 Swing Rd., P.O. Box 18300, Greensboro, NC 27419–8300. *Active Ingredient:* Oxathiapiprolin. *Product Type:* Fungicide. *Proposed Uses:* New food uses on citrus fruit crop group 10–10. *Contact:* RD.

3. *EPA Registration Number:* 352–890. *Docket ID Number:* EPA–HQ–OPP–2016–0049. *Applicant:* E.I. du Pont de Nemours and Company, Inc., DuPont Crop Protection, Stine-Haskell Research

Center, P.O. Box 30, Newark, DE 19714–0300. *Active Ingredient:* Oxathiapiprolin. *Product Type:* Fungicide. *Proposed Uses:* New food uses on citrus fruit crop group 10–10 and for soybean and sunflower seed treatment. *Contact:* RD.

4. *EPA Registration Number:* 499–540. *Docket ID Number:* EPA–HQ–OPP–2016–0184. *Applicant:* BASF Corp., 26 Davis Dr., Research Triangle Park, NC 27709–3528. *Active Ingredients:* Dinotefuran, prallethrin, and pyriproxyfen. *Product Type:* Insecticide. *Proposed Use:* Mattress. *Contact:* RD.

5. *EPA Registration Number:* 73049–500. *Docket ID Number:* EPA–HQ–OPP–2016–0065. *Applicant:* Valent BioSciences Corp., 870 Technology Way, Libertyville, IL 60048. *Active Ingredient:* Methyl salicylate. *Product Type:* Plant regulator (induced resistance promoter). *Proposed Uses:* All vegetables and tobacco. *Contact:* BPPD.

6. *EPA Registration Number:* 83019–1. *Docket ID Number:* EPA–HQ–OPP–2016–0219. *Applicant:* BioSafe, Inc., 2425 Sidney St., Pittsburgh, PA 15203. *Active Ingredient:* 1-Octadecanaminium, N,N-dimethyl-N-(3-(trimethoxysilyl)propyl)-, chloride. *Product Type:* Antimicrobial. *Proposed Use:* Indirect food use contact. *Contact:* AD.

7. *EPA Registration Numbers:* 87485–1 and 87485–2. *Docket ID Number:* EPA–HQ–OPP–2016–0162. *Applicant:* DSM Food Specialties B.V., P.O. Box 1, 2600 MA Delft, The Netherlands (c/o Keller and Heckman, LLP, 1001 G St. NW., Washington, DC 20001). *Active Ingredient:* Natamycin. *Product Type:* Fungistat. *Proposed Uses:* Citrus, pome, and stone fruit crop groups; avocado; kiwi; mango; and pomegranate. *Contact:* BPPD.

Authority: 7 U.S.C. 136 *et seq.*

Dated: May 3, 2016.

Mark A. Hartman,

Acting, Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

[FR Doc. 2016–10992 Filed 5–9–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9946–12–Region 9]

Highland Plating Removal Site, Los Angeles, CA; Notice of Proposed CERCLA Settlement Agreement and Order on Consent

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; request for comment.

SUMMARY: In accordance with Section 122(i) of the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended (CERCLA), 42 U.S.C. 9622(i), notice is hereby given of a proposed administrative settlement with 7007 W. Romaine (LA) LLC, for a removal action by a bona fide prospective purchaser, concerning the Highland Plating Removal Site in Los Angeles, California. EPA enters the settlement pursuant to Section 122(h)(1) of CERCLA, 42 U.S.C. 9622(h)(1). The settlement provides for the completion of a removal action at a fire-ravaged plating facility in a residential and light industrial community, and is premised on the status of 7007 W. Romaine (LA) LLC as a bona fide prospective purchaser. The settlement does not require cost recovery, but includes a covenant not to sue pursuant to Sections 106 or 107(a) of CERCLA, 42 U.S.C. 9606 or 9607(a). For thirty (30) days following the date of publication of this notice in the **Federal Register**, the Agency will receive written comments relating to the settlement. The Agency will consider all comments received and may modify or withdraw its consent to the settlement if comments received disclose facts or considerations that indicate the proposed settlement is inappropriate, improper, or inadequate. The Agency's response to any comments received will be available for public inspection at 75 Hawthorne Street, San Francisco, CA 94105.

DATES: Pursuant to Section 122(i) of CERCLA, EPA will receive written comments relating to this proposed settlement for thirty (30) days following the date of publication of this notice in the **Federal Register**.

ADDRESSES: The proposed settlement is available for public inspection at EPA Region IX, 75 Hawthorne Street, San Francisco, California. A copy of the proposed settlement may be obtained from J. Andrew Helmlinger, EPA Region IX, 75 Hawthorne Street, ORC–3, San Francisco, CA 94105, telephone number 415–972–3904. Comments should reference the Highland Plating Removal Site, Los Angeles, California and should be addressed to Mr. Helmlinger at the above address.

FOR FURTHER INFORMATION CONTACT: J. Andrew Helmlinger, Assistant Regional Counsel (ORC–3), Office of Regional Counsel, U.S. EPA Region IX, 75 Hawthorne Street, San Francisco, CA 94105; phone: (415) 972–3904; fax: (417) 947–3570; email: *helmlinger.andrew@epa.gov.*

Dated: April 28, 2016.

Enrique Manzanilla,

Director, Superfund Division, U.S. EPA, Region IX.

[FR Doc. 2016–10986 Filed 5–9–16; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL DEPOSIT INSURANCE CORPORATION

FDIC Advisory Committee on Economic Inclusion (ComE–IN); Notice of Meeting

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice of open meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92–463 (Oct. 6, 1972), 5 U.S.C. App. 2, notice is hereby given of a meeting of the FDIC Advisory Committee on Economic Inclusion, which will be held in Washington, DC. The Advisory Committee will provide advice and recommendations on initiatives to expand access to banking services by underserved populations.

DATES: Wednesday, May 25, 2016, from 9:00 a.m. to 4:00 p.m.

ADDRESSES: The meeting will be held in the FDIC Board Room on the sixth floor of the FDIC Building located at 550 17th Street NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Requests for further information concerning the meeting may be directed to Mr. Robert E. Feldman, Committee Management Officer of the FDIC, at (202) 898–7043.

SUPPLEMENTARY INFORMATION:

Agenda: The agenda will be focused on mobile banking research, payment system modernization, banks' efforts to serve the unbanked and underbanked, and opportunities to expand economic inclusion for persons with disabilities. The agenda may be subject to change. Any changes to the agenda will be announced at the beginning of the meeting.

Type of Meeting: The meeting will be open to the public, limited only by the space available on a first-come, first-served basis. For security reasons, members of the public will be subject to security screening procedures and must present a valid photo identification to enter the building. The FDIC will provide attendees with auxiliary aids (*e.g.,* sign language interpretation) required for this meeting. Those attendees needing such assistance should call (703) 562–6067 (Voice or TTY) at least two days before the meeting to make necessary arrangements. Written statements may be filed with the committee before or after the meeting. This ComE–IN meeting will be Webcast live via the Internet at: *https://fdic.primetime.mediaplatform.com/#/channel/1384299229422/Advisory+Committee+on+Economic+Inclusion*. Questions or troubleshooting help can be found at the same link. For optimal viewing, a high speed internet connection is recommended. The ComE–IN meeting videos are made available on-demand approximately two weeks after the event.

Dated: May 5, 2016.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary, Federal Deposit Insurance Corporation.

[FR Doc. 2016–10947 Filed 5–9–16; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL RESERVE SYSTEM

Solicitation of Applications for Membership on the Community Advisory Council

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Notice.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) established the Community Advisory Council (the "CAC") as an advisory committee to the Board on issues affecting consumers and communities. This Notice advises individuals who wish to serve as CAC members of the opportunity to be considered for the CAC.

DATES: Applications received on or before July 11, 2016 will be considered for selection to the CAC for terms beginning January 1, 2017.

ADDRESSES: Individuals who are interested in being considered for the CAC may submit an application via the Board's Web site or via email. The application can be accessed at *http://www.federalreserve.gov/secure/CAC/Application/*. Emailed submissions can be sent to *CCA–CAC@frb.gov*. The information required for consideration is described below.

If electronic submission is not feasible, submissions may be mailed to the Board of Governors of the Federal Reserve System, Attn: Community Advisory Council, Mail Stop N–805, 20th Street and Constitution Ave. NW., Washington, DC 20551.

FOR FURTHER INFORMATION CONTACT: Andrew Dumont, Senior Community Development Analyst, Division of Consumer and Community Affairs, Board of Governors of the Federal Reserve System, 20th Street and Constitution Ave. NW., Washington, DC 20551, (202) 452–2412, or *CCA–CAC@frb.gov*. Telecommunications Device for the Deaf (TDD) users may contact (202) 263–4869.

SUPPLEMENTARY INFORMATION: The Board created the Community Advisory Council (CAC) as an advisory committee to the Board on issues affecting consumers and communities. The CAC is composed of a diverse group of experts and representatives of consumer and community development organizations and interests, including from such fields as affordable housing, community and economic development, employment and labor, financial services and technology, small business, and asset and wealth building. CAC members meet semiannually with the members of the Board in Washington, DC to provide a range of perspectives on the economic circumstances and financial services needs of consumers and communities, with a particular focus on the concerns of low- and moderate-income consumers and communities. The CAC complements two of the Board's other advisory councils—the Community Depository Institutions Advisory Council (CDIAC) and the Federal Advisory Council (FAC)—whose members represent depository institutions.

The CAC serves as a mechanism to gather feedback and perspectives on a wide range of policy matters and emerging issues of interest to the Board of Governors and aligns with the Federal Reserve's mission and current responsibilities. These responsibilities include, but are not limited to, banking supervision and regulatory compliance (including the enforcement of consumer protection laws), systemic risk oversight and monetary policy decision-making, and, in conjunction with the Office of the Comptroller of the Currency (OCC) and Federal Deposit Insurance Corporation (FDIC), responsibility for implementation of the Community Reinvestment Act (CRA).

This Notice advises individuals of the opportunity to be considered for appointment to the CAC. To assist with the selection of CAC members, the Board will consider the information submitted by the candidate along with other publicly available information that it independently obtains.

Council Size and Terms

The CAC consists of at least 15 members. The Board will select four members in the fall of 2016 to replace current members whose terms will expire on December 31, 2016. The newly appointed members will serve three-year terms that will begin on January 1, 2017. If a member vacates the CAC before the end of the three-year term, a replacement member will be appointed to fill the unexpired term.

Application

Candidates may submit applications by one of three options:

- Online: Complete the application form on the Board's Web site at *http://www.federalreserve.gov/secure/CAC/Application/*.
- Email: Submit all required information to *CCA–CAC@frb.gov*.
- Postal Mail: If electronic submission is not feasible, submissions may be mailed to the Board of Governors of the Federal Reserve System, Attn: Community Advisory Council, Mail Stop N–805, 20th Street and Constitution Ave. NW., Washington, DC 20551.

Below are the application fields. Asterisks (*) indicate required fields.

- Full Name*
- Email Address*
- Phone Number*
- Postal Mail Street Address*
- Postal Mail City*
- Postal Zip Code*
- Organization*
- Title*
- Organization Type (select one)*
  - ○ For Profit
    - ▪ Community Development Financial Institution (CDFI)
    - ▪ Non-CDFI Financial Institution
    - ▪ Financial Services
    - ▪ Professional Services
    - ▪ Other
  - ○ Non-Profit
    - ▪ Advocacy
    - ▪ Association
    - ▪ Community Development Financial Institution (CDFI)
    - ▪ Educational Institution
    - ▪ Foundation
    - ▪ Service Provider
    - ▪ Think Tank/Policy Organization
    - ▪ Other
  - ○ Government
- Primary Area of Expertise (select one)*
  - ○ Civil rights
  - ○ Community development finance
  - ○ Community reinvestment and stabilization
  - ○ Consumer protection
  - ○ Economic and small business development
  - ○ Employment and labor
  - ○ Financial services and technology
  - ○ Household wealth building and financial stability
  - ○ Housing and mortgage finance
  - ○ Rural issues

- ○ Other (please specify)
- Secondary Area of Expertise (select one)
  - ○ Civil rights
  - ○ Community development finance
  - ○ Community reinvestment and stabilization
  - ○ Consumer protection
  - ○ Economic and small business development
  - ○ Employment and labor
  - ○ Financial services and technology
  - ○ Household wealth building and financial stability
  - ○ Housing and mortgage finance
  - ○ Rural issues
  - ○ Other (please specify)
- Resume*
  - ○ The resume should include information about past and present positions you have held, dates of service for each, and a description of responsibilities.
- Cover Letter*
  - ○ The cover letter should explain why you are interested in serving on the CAC as well as what you believe are your primary qualifications.
- Additional Information
  - ○ At your option, you may also provide additional information about your qualifications.

Qualifications

The Board is interested in candidates with knowledge of fields such as affordable housing, community and economic development, employment and labor, financial services and technology, small business, and asset and wealth building, with a particular focus on the concerns of low- and moderate-income consumers and communities. Candidates do not have to be experts on all topics related to consumer financial services or community development, but they should possess some basic knowledge of these areas and related issues. In appointing members to the CAC, the Board will consider a number of factors, including diversity in terms of subject matter expertise, geographic representation, and the representation of women and minority groups.

CAC members must be willing and able to make the necessary time commitment to participate in organizational conference calls and prepare for and attend meetings two times per year (usually for two days). The meetings will be held at the Board's offices in Washington, DC. The Board will provide a nominal honorarium and will reimburse CAC members only for their actual travel expenses subject to Board policy.

By order of the Board of Governors of the Federal Reserve System, acting through the Director of the Division of Consumer and Community Affairs under delegated authority, May 4, 2016.

Margaret M. Shanks,

Deputy Secretary of the Board.

[FR Doc. 2016–10945 Filed 5–9–16; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than June 6, 2016.

A. Federal Reserve Bank of Minneapolis (Jacquelyn K. Brunmeier, Assistant Vice President) 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *Peoples Equity Corporation, Wells, Minnesota;* to acquire 100 percent of Paragon Bank, Wells, Minnesota.

B. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. *First Gothenburg Bancshares, Inc., Gothenburg, Nebraska;* to acquire 100 percent of the voting shares of Nebanco, Inc., Wallace, Nebraska, and thereby indirectly acquire Farmers State Bank, Wallace, Nebraska.

Board of Governors of the Federal Reserve System, May 5, 2016.

Michael J. Lewandowski,

Associate Secretary of the Board.

[FR Doc. 2016–10982 Filed 5–9–16; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL TRADE COMMISSION

Agency Information Collection Activities; Submission for OMB Review; Comment Request

AGENCY: Federal Trade Commission ("Commission" or "FTC").

ACTION: Notice.

SUMMARY: The information collection requirements described below will be submitted to the Office of Management and Budget ("OMB") for review, as required by the Paperwork Reduction Act ("PRA"). The FTC seeks public comments on its proposal to extend for an additional three years the current PRA clearance for information collection requirements contained in its regulation "Duties of Furnishers of Information to Consumer Reporting Agencies" ("Information Furnishers Rule"), which applies to certain motor vehicle dealers, and its shared enforcement with the Consumer Financial Protection Bureau ("CFPB") of the furnisher provisions (subpart E) of the CFPB's Regulation V regarding other entities. That clearance expires on August 31, 2016.

DATES: Comments must be submitted on or before June 9, 2016.

ADDRESSES: Interested parties may file a comment online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write "Information Furnishers Rule, PRA Comment, P135407," on your comment and file your comment online at *https://ftcpublic.commentworks.com/ftc/infofurnishersrulepra2,* by following the instructions on the web-based form. If you prefer to file your comment on paper, mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex J), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex J), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Monique Einhorn, Attorney, Division of Privacy and Identity Protection, Bureau of Consumer Protection, (202) 326–

2575, 600 Pennsylvania Ave. NW., CC–8232, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: On February 23, 2016, the Commission sought comment on the information collection requirements associated with the Information Furnishers Rule and the Commission's shared enforcement with the CFPB of the furnisher provisions in subpart E of the CFPB's Regulation V. 81 FR 8959. No relevant comments were received. Pursuant to the OMB regulations, 5 CFR part 1320, that implement the PRA, 44 U.S.C. 3501 *et seq.*, the FTC is providing this second opportunity for public comment while seeking OMB approval to renew the pre-existing clearance for those information collection requirements. For more details about the Rule requirements, the background behind these information collection provisions, and the basis for the calculations summarized below, see 81 FR 8959. The burden figures below reflect solely the FTC's estimates assigned to itself, including a portion reflective of its sole enforcement authority for certain motor vehicle dealers subject to the FTC rule.[1]

Title: Duties of Furnishers of Information to Consumer Reporting Agencies.

OMB Control Number: 3084–0144.

Type of Review: Extension of currently approved collection.

Estimated Annual Burden:

Section 660.3 of FTC Rule/Section 1022.42 of CFPB Rule:
7,972 hours and $428,017[2] in associated labor costs
Section 660.4 of FTC Rule/Section 1022.43 of CFPB Rule:
2,635 hours and $60,131[3] in associated labor costs

Thus, total estimated burden under the above-noted regulatory sections is 10,607 hours and $488,148 in associated labor costs. Commission staff believes that the Information Furnishers Rule and subpart E of Regulation V impose negligible capital or other non-labor costs, as the affected entities are already likely to have the necessary supplies and/or equipment (*e.g.*, offices and computers) for the associated information collection provisions.

Request for Comment

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before June 9, 2016. Write "Information Furnishers Rule, PRA Comment, P135407" on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including to the extent practicable, on the public Commission Web site, at *http://www.ftc.gov/os/publiccomments.shtm.* As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Web site.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any "[t]rade secret or any commercial or financial information which is . . . privileged or confidential" as provided in Section 6(f) of the FTC Act 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c).[4] Your comment will be kept confidential only if the FTC General Counsel grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at *https://ftcpublic.commentworks.com/ftc/infofurnishersrulepra2*, by following the instructions on the web-based form. If this Notice appears at *http://www.regulations.gov/#!home*, you also may file a comment through that Web site.

If you file your comment on paper, write "Information Furnishers Rule, PRA Comment, P135407" on your comment and on the envelope, and mail or deliver it to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex J), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex J), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Comments on the disclosure requirements subject to review under the PRA should additionally be submitted to OMB. If sent by U.S. mail, they should be addressed to Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for the Federal Trade Commission, New Executive Office Building, Docket Library, Room 10102, 725 17th Street NW., Washington, DC 20503. Comments sent to OMB by U.S. postal mail, however, are subject to delays due to heightened security precautions. Thus, comments instead should be sent by facsimile to (202) 395–5806.

The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before June 9, 2016. For information on the Commission's privacy policy, including routine uses permitted by the

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[1] The FTC retains rulemaking authority for its Information Furnishers Rule solely for motor vehicle dealers described in section 1029(a) of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Pub. L. 111–203, 124 Stat. 1376 (2010)) that are predominantly engaged in the sale and servicing of motor vehicles, the leasing and servicing of motor vehicles, or both.

[2] This is an increase from the labor cost estimate in the February 23, 2016 **Federal Register** Notice, attributable to an intervening annual release from the Bureau of Labor Statistics. Within it, the mean hourly wage for "Training and development managers" rose from the previously shown amount of $53.38 to $53.69. *See http://www.bls.gov/news.release/ocwage.t01.htm* "Occupational Employment and Wages—May 2015," Bureau of Labor Statistics, U.S. Department of Labor, released March 30, 2016, Table 1 ("National employment and wage data from the Occupational Employment Statistics survey by occupation, May 2015") (hereinafter, "BLS Table 1").

[3] This, too, is an increase from the labor cost estimate in the February 23, 2016 **Federal Register** Notice, attributable to an averaging of updated Bureau of Labor Statistics mean hourly wages for potentially analogous employee types: First-line supervisors of office and administrative support workers ($27.01); accounting and auditing clerks ($18.74); brokerage clerks ($24.83); eligibility interviewers, government programs ($20.69). *See* BLS Table 1. This averages out to $22.82 per hour, rounded.

[4] In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c), 16 CFR 4.9(c).

Privacy Act, see *http://www.ftc.gov/ftc/privacy.htm.*

David C. Shonka,

Acting General Counsel.

[FR Doc. 2016–11035 Filed 5–9–16; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0032; Docket 2016–0053; Sequence 30]

Information Collection; Contractor Use of Interagency Fleet Management System Vehicles

AGENCIES: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for public comments regarding an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement concerning contractor use of interagency fleet management system vehicles.

DATES: Submit comments on or before July 11, 2016.

ADDRESSES: Submit comments identified by Information Collection 9000–0032, Contractor Use of Interagency Fleet Management System Vehicles, by any of the following methods:

- Regulations.gov: *http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by searching the OMB control number. Select the link "Submit a Comment" that corresponds with "Information Collection 9000–0032, Contractor Use of Interagency Fleet Management System Vehicles". Follow the instructions provided at the "Submit a Comment" screen. Please include your name, company name (if any), and "Information Collection 9000–0032, Contractor Use of Interagency Fleet Management System Vehicles" on your attached document.
- Mail: General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405. ATTN: Ms. Flowers/IC 9000–0032, Contractor Use of Interagency Fleet Management System Vehicles.

Instructions: Please submit comments only and cite Information Collection 9000–0032, Contractor Use of Interagency Fleet Management System Vehicles, in all correspondence related to this collection. Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Ms. Mahruba Uddowla, Procurement Analyst, Office of Governmentwide Acquisition Policy, GSA, 703–605–2868 or email at *mahruba.uddowla@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. Purpose

If it is in the best interest of the Government, the contracting officer may authorize cost-reimbursement contractors to obtain, for official purposes only, interagency fleet management system (IFMS) vehicles and related services. Federal Acquisition Regulation (FAR) 51.205 and the clause at FAR 52.251–2, Interagency Fleet Management System (IFMS) Vehicles and Related Services are to be used in solicitations and contracts when a cost reimbursement contract is contemplated and the contracting officer may authorize the contractor to use interagency fleet management system (IFMS) vehicles and related services.

Before a contracting officer may authorize cost-reimbursement contractors to obtain IFMS vehicles and related services, the contracting officer must have, among other requirements:

- A written statement that the contractor will assume, without the right of reimbursement from the Government, the cost or expense of any use of the IFMS vehicles and services not related to the performance of the contract;
- Evidence that the contractor has obtained motor vehicle liability insurance covering bodily injury and property damage, with limits of liability as required or approved by the agency, protecting the contractor and the Government against third-party claims arising from the ownership, maintenance, or use of an IFMS vehicle; and
- Considered any recommendations of the contractor. The information is used by the Government to determine whether it is in the Government's best interest to authorize a cost-reimbursement contractor, for official purposes only, to use IFMS vehicles and related services.

Authorized contractors shall submit requests for IFMS vehicles and related services in writing to the appropriate GSA point of contact in accordance with the FAR. Contractors' requests for vehicles or related services must include:

- Two copies of the agency authorization;
- The number of vehicles and related services required and period of use;
- A list of employees who are authorized to request the vehicles or related services;
- A listing of equipment authorized to be serviced; and
- Billing instructions and address.

B. Annual Reporting Burden

Respondents: 132.

Responses per Respondent: 1.0.

Total Annual Responses: 132.

Hours per Response: 1.0.

Total Burden Hours: 132.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the Federal Acquisition Regulations (FAR), and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405, telephone 202–501–4755. Please cite OMB Control No. 9000–0032, Contractor Use of Interagency Fleet Management System Vehicles, in all correspondence.

Dated: May 5, 2016.

Lorin S. Curit,

Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2016–10941 Filed 5–9–16; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0055; Docket 2015–0055; Sequence 23]

Submission for OMB Review; Freight Classification Description

AGENCIES: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for public comments regarding an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement concerning freight classification description. A notice was published in the **Federal Register** at 80 FR 74105 on November 27, 2015. No comments were received.

DATES: Submit comments on or before June 9, 2016.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Office of Information and Regulatory Affairs of OMB, Attention: Desk Officer for GSA, Room 10236, NEOB, Washington, DC 20503. Additionally submit a copy to GSA by any of the following methods:

- *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by searching the OMB control number. Select the link "Submit a Comment" that corresponds with "Information Collection 9000–0055, Freight Classification Description". Follow the instructions provided at the "Submit a Comment" screen. Please include your name, company name (if any), and "Information Collection 9000–0055, Freight Classification Description" on your attached document.
- *Mail:* General Services Administration, Regulatory Secretariat Division (MVCB), 1800 First Street NW., Washington, DC 20405. ATTN: Ms. Flowers/IC 9000–0055, Freight Classification Description.

Instructions: Please submit comments only and cite Information Collection 9000–0055, Freight Classification Description, in all correspondence related to this collection. Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Mr. Curtis E. Glover, Sr., Procurement Analyst, Office of Acquisition Policy, at 202–501–1448 or via email at *curtis.glover@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. Purpose

The Government is required to provide, in solicitations, a complete description of the supplies to be acquired and the packing requirements to determine transportation (freight rate) charges for the evaluation of offers. Generally, the freight rate for supplies is based on the ratings applicable to the freight classification description published in the National Motor Freight Classification (for carriers) and the Uniform Freight Classification (for rail) filed with Federal and State regulatory bodies.

When the Government purchases supplies that are new to the supply system, nonstandard, or modifications of previously shipped supplies, and different freight classifications may apply, per FAR clause 52.247–53, offerors are requested to indicate the full Uniform Freight Classification or National Motor Freight Classification description applicable to the supplies. The Government will use these descriptions as well as other information available to determine the classification description most appropriate and advantageous to the government.

B. Annual Reporting Burden

Respondents: 3,000.

Responses per Respondent: 3.

Annual Responses: 9,000.

Hours per Response: .167.

Total Burden Hours: 1,503.

Affected Public: Business other for-profit entities and not-for-profit institutions.

Frequency: On occasion.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the Federal Acquisition Regulations (FAR), and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 First Street NW., Washington, DC 20405, telephone 202–501–4755. Please cite OMB Control No. 9000–0055, Freight Classification Description, in all correspondence.

Dated: May 5, 2016.

Lorin S. Curit,

Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2016–10942 Filed 5–9–16; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0069; Docket 2016–0053; Sequence 12]

Submission for OMB Review; Indirect Cost Rates

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for comments regarding an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division will be submitting to the Office of Management

and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement concerning Indirect Cost Rates. A notice was published in the **Federal Register** at 81 FR 10861 on March 2, 2016. No comments were received.

DATES: Submit comments on or before June 9, 2016.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Office of Information and Regulatory Affairs of OMB, Attention: Desk Officer for GSA, Room 10236, NEOB, Washington, DC 20503. Additionally submit a copy to GSA by any of the following methods:

- Regulations.gov: *http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by searching the OMB control number. Select the link "Submit a Comment" that corresponds with "Information Collection 9000–0069, Indirect Cost Rates". Follow the instructions provided at the "Submit a Comment" screen. Please include your name, company name (if any), and "Information Collection 9000–0069, Indirect Cost Rates" on your attached document.
- Mail: General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405. ATTN: Ms. Flowers/IC 9000–0069, Indirect Cost Rates.

Instructions: Please submit comments only and cite Information Collection 9000–0069, Indirect Cost Rates, in all correspondence related to this collection. Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Mr. Curtis E. Glover, Sr., Procurement Analyst, Contract Policy Division, at 202–501–1448, or via email at *curtis.glover@gsa.gov.*

A. Purpose

The contractor's proposal of final indirect cost rates is necessary for the establishment of rates used to reimburse the contractor for the costs of performing under the contract. The supporting cost data are the cost accounting information normally prepared by organizations under sound management and accounting practices.

The proposal and supporting data is used by the contracting official and auditor to verify and analyze the indirect costs and to determine the final indirect cost rates or to prepare the Government negotiating position if negotiation of the rates is required under the contract terms.

B. Annual Reporting Burden

Respondents: 3,000.

Responses per Respondent: 1.

Annual Responses: 3,000.

Hours per Response: 2,188.

Total Burden Hours: 6,564,000.

Affected Public: Businesses or other for-profit entities and not-for-profit institutions.

Frequency: On occasion.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the FAR, and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405, telephone 202–501–4755. Please cite OMB Control No. 9000–0069, Indirect Cost Rates, in all correspondence.

Dated: May 5, 2016.

Lorin S. Curit,

Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2016–10943 Filed 5–9–16; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–5520–N]

Announcement of Requirements and Registration for "A Bill You Can Understand" Design and Innovation Challenge: Help Patients Understand Their Medical Bills and the Financial Aspect of Health

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces a Challenge to engage those in the health care community working on these issues, as well as new players from other industries, such as human-centered design and digital technology, to help in redesigning the "Medical Bill" or the "Medical Billing Process."

DATES: *Submission Dates:* May 9, 2016, 12:01 a.m., Eastern daylight time (e.d.t.) through August 10, 2016, 11:59 p.m., e.d.t.

Judging Dates: August 20 through September 10, 2016.

Winners Announced: September 25 through 28, 2016.

FOR FURTHER INFORMATION CONTACT: Ben Shannon, Communications Advisor, Office of the Assistant Secretary for Public Affairs, Department of Health and Human Services, 200 Independence Avenue SW., Washington, DC 20201, phone (202) 205–2819, email *ben.shannon@hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Patients in the United States often have difficulty understanding the medical billing process. Currently, there is no standard for consumer medical billing documents, and bills vary in content, presentation, and use of jargon. Consumers also receive bills from multiple sources and may not understand the rationale for each bill, or know that they will be receiving multiple bills for one episode of care.

HHS recognizes that many health care organizations have been doing important work to address the complex problems that individuals face as they navigate the medical billing process. A national design and innovation challenge is a unique way to both support these ongoing efforts and catalyze innovation.

II. Provisions of the Notice

The Challenge has two objectives:

- *Objective 1:* "Redesigning the Medical Bill": Improving the medical bill itself. That is, making it more readable and easier for the consumer to understand.
- *Objective 2:* "Redesigning the Medical Billing Process": Improving the overall medical billing process. Submissions could address any step in the consumer journey from the medical encounter to afterward (for example, providing information at discharge on the medical billing process, developing a consolidated bill, creating a unified billing portal, etc.).

HHS intends for the challenge to produce conceptual solutions and frames that will help health systems and payers continue to make improvements in reducing the complexity of medical bills and improving the financial aspect of health from the patient's perspective. HHS anticipates health systems and payers will find ways to work with Challenge winners to evaluate their solutions for implementation and testing in the real world after the Challenge concludes.

A. Subject of the Challenge Competition

"A Bill You Can Understand" design and innovation challenge will invite participants to design a medical bill that is easier to understand, as well as reinvent cost of care estimation and the medical billing journey with the goal of improving the patient financial experience. Participants will be asked to submit entries that improve both the design of the medical bill and patient experience of the medical billing process. Submissions will include the (1) design concept for the redesigned medical bill, (2) journey map or wireframe for the redesigned patient experience, (3) written explanation of submission, and (3) video explanation of submission. Specific criteria for the written and video explanations will be provided on the Challenge Web site. These may include but are not limited to explaining how the redesign will better empower patients to understand the financial information provided on their medical bill and take appropriate action and vision for an improved patient financial experience. The challenge is sponsored by AARP, administrated by Mad*Pow, an experience design agency, and organized in collaboration with HHS.

B. Eligibility Rules for Participating in the Competition

The Challenge is open to any contestant, defined as (1) a business or non-profit entity or (2) an individual or team of no more than 5 U.S. citizens or permanent residents of the United States who are 18 years of age or older at the time of entry. All individual members of a team must meet the eligibility requirements.

To be eligible to win a prize under this challenge, an individual or entity—

(1) Shall have registered to participate in the competition under the rules issued by CMS;

(2) Shall have complied with all the requirements under this Notice, the rules for participants referenced herein below, and the requirements set forth in 15 U.S.C. 3719;

(3) In the case of a private entity, shall be incorporated in and maintain a primary place of business in the United States, and in the case of an individual, whether participating singly or in a group, shall be a citizen or permanent resident of the United States; and

(4) May not be a Federal entity or Federal employee acting within the scope of their employment. Federal employees seeking to participate in this contest outside the scope of their employment should consult their ethics official prior to developing their submission.

(5) May not be employees of CMS, judges of the Challenge, or any other party involved with the design, production, execution, or distribution of the Challenge or their immediate family (spouse, parents or step-parents, siblings and step-siblings, and children and step-children).

(6) May not be the trustees, directors, shareholders, employees, clients (with respect to Mad*Pow only), contractors, agents, representatives and affiliates of AARP, Mad*Pow and any entity associated with the funding, administration, judging, or processing of the Challenge and the members of the immediate family which includes a person's spouse/domestic partner and the parents, siblings, children and grandchildren of the person and his or her spouse/domestic partner.

(7) Federal grantees may not use Federal funds to develop COMPETES Act challenge applications unless consistent with the purpose of their grant award.

(8) Federal contractors may not use Federal funds from a contract to develop COMPETES Act challenge applications or to fund efforts in support of a COMPETES Act challenge submission.

An individual or entity shall not be deemed ineligible because the individual or entity used Federal facilities or consulted with Federal employees during a competition if the facilities and employees are made available to all individuals and entities participating in the competition on an equitable basis.

By entering, each contestant agrees to:

(a) Comply with, and be bound by, these official rules and the decisions of the Challenge and judges which are binding and final in all matters relating to this Challenge;

(b) assume any and all risks and waive claims against the federal government and its related entities, except in the case of willful misconduct, for any injury, death, damage, or loss of property, revenue, or profits, whether direct, indirect, or consequential, arising from the contestant's participation in the Challenge, whether the injury, death, damage, or loss arises through negligence or otherwise. The contestant/submitter shall be liable for, and shall indemnify and hold harmless the government against, all actions or claims for any claim, demand, judgment, or other allegation arising from alleged violation of an individual's trademark, copyright, or other legally protected interest in challenge entries submitted to Mad*Pow. Provided, however, that contestants are not required to waive claims arising out of the unauthorized use or disclosure by AARP and/or Mad*Pow of the intellectual property, trade secrets, or confidential business information of the contestant.

(c) Be responsible for obtaining their own liability insurance to cover claims by any third party for death, bodily injury, or property damage, or loss resulting from an activity carried out in connection with participation in the Challenge, and claims by the federal government for damage or loss to government property resulting from such an activity; and

(d) Indemnify the federal government against third party claims for damages arising from or related to Challenge activities.

Based on the subject matter of the Challenge, the type of work that it will possibly require, as well as an analysis of the likelihood of any claims for death, bodily injury, property damage, or loss potentially resulting from Challenge participation, no individual (whether competing singly or in a group) or entity participating in the Challenge is required to obtain liability insurance or demonstrate financial responsibility in order to participate in this Challenge.

Contestants who are determined at any time to have violated the eligibility criteria will be disqualified from the Challenge.

C. Registration Process for Participants

The entry period for the Challenge will begin as stated in the **DATES** section of this notice. Contestants can enter the Challenge by visiting the Challenge Web site at *http://www.abillyoucanunderstand.com,* reviewing official challenge rules and guidelines, and registering a submission by submitting the Official Entry Form according to the instructions posted on the Challenge Web site. Each Submission entered into the Challenge must meet the "Submission Requirements" (any submission that, in the Challenge Judges' sole discretion, violates submission criteria will be disqualified). Once a submission is made, a team is prohibited from making any changes or alterations to the product described in its submission until the evaluation of the entries is completed.

D. Amount of the Prize

Two winning contestants will be selected for the following prizes:

- *Prize 1—$5000:* Most Improved Medical Bill Design (Focusing on the design of the bill itself).
- *Prize 2—$5000:* Transformational Approach to Medical Cost Estimation and Billing Process (Focusing on what the patient sees and does throughout the process).

E. Payment of the Prize

Prizes awarded under this competition will be paid by check and may be subject to federal income taxes. The prizes are donated by a private donor, AARP, Inc.

F. Basis Upon Which the Winners Will Be Selected

The entries will be judged by HHS leadership with consideration of input from an advisory panel of individuals in compliance with the requirements of the COMPETES Act. Judges will be fair and impartial, may not have a personal or financial interest in, or be an employee, officer, director, or agent of, any entity that is a registered participant in the competition, and may not have a familial or financial relationship with an individual who is a registered contestant. Judges will be named after the Challenge begins. The judging panel will make decisions based on the following criteria:

Criteria for Both Prizes 1 and 2:

- Contains all Necessary Data and Information.
- Usefulness and Understandability of Patient Facing Materials (Bill or Otherwise).
- Adherence to Plain Language Guidelines.
- Transparency of Data (Including How the Data is Translated and Explained).
- Uniqueness and Creativity of Solution.

Additional Specific Criteria for Prize 1: Most Improved Medical Bill Design (Focusing on the design of the bill itself):

- Addresses Issues and Opportunities Associated with Bill Design.
- Incremental Innovation—Works with Existing Models (Workflow, Data, Technology, Patient Facing Materials).

Additional Specific Criteria for Prize 2: Transformational Approach to Medical Cost Estimation and Billing Process (Focusing on what the patient sees and does throughout the process):

- Addresses Issues and Opportunities associated with Medical Cost Estimation and Billing Process.
- Alignment with Modern Consumer Expectations.
- Future Forward Innovation—Evolves Existing Models (Workflow, Data, Technology, Patient Facing Materials).

The details of these criteria are provided on the Challenge Web site at *http://www.abillyoucanunderstand.com.*

G. Additional Information

More information on the topic area can be found in the participant resource packet on the Challenge Web site at *http://www.abillyoucanunderstand.com.*

H. Regarding Copyright/Intellectual Property

Each contestant, by submitting any design, irrevocably grants to HHS a royalty-free, irrevocable, perpetual, non-exclusive, transferable license to use, reproduce, modify, edit, adapt, publish, and display such design in whole or in part, on a worldwide basis, and to incorporate it into other works, in any form, media or technology now known or later developed, including for promotional, marketing, educational, training and other public health purposes consistent with HHS and/or CMS' mission and without further compensation to the contestant or any other person or entity. For clarity, each contestant's design and all rights, including intellectual property rights, title, and interest therein and thereto lie exclusively with each contestant. There is no agreement of sale, and no title, interest, or intellectual property rights or other ownership of the design are transferred per the official rules of the Challenge, except as explicitly stated here. HHS shall not be responsible for mediating disputes that arise relating to intellectual property ownership.

Upon submission, contestants warrant that they are the sole author and owner of the Challenge Submission, and that the submission completely originates with the contestant, that it does not infringe upon any copyright or any other rights of any third party of which contestant(s) is aware, and is free of malware.

The official rules of the Challenge are provided on the Challenge Web site at *http://www.abillyoucanunderstand.com.*

I. Compliance With Rules and Contacting Contest Winners

Contest winners must comply with all terms and conditions of the official rules; winning is contingent upon fulfilling all requirements herein. The initial finalists will be notified by email, telephone, or mail after the date of the judging. Awards may be subject to federal income taxes, and HHS will comply with the Internal Revenue Service withholding and reporting requirements, where applicable.

J. Privacy

If contestants choose to provide Mad*Pow or HHS with personal information by registering or filling out the submission form through the Challenge Web site, that information is used to respond to contestants in matters regarding their submission, announcements of entrants, finalists, and winners of the contest. Information is not collected for commercial marketing. Winners are permitted to cite that they won this Challenge.

K. General Conditions

HHS reserves the right to cancel, suspend, and/or modify the Challenge, or any part of it, for any reason, at HHS' sole discretion.

Participation in this contest constitutes contestants' full and unconditional agreement to abide by the official rules found at *http://www.abillyoucanunderstand.com* and *www.Challenge.gov.*

III. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Dated: May 2, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2016–10980 Filed 5–9–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Clinical Trial Design Considerations for Malaria Drug Development Media; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop regarding clinical trial design considerations for malaria drug development. FDA is interested in discussing the scientific challenges pertaining to malaria drug development and malaria parasite detection methods used as endpoints in clinical trials. This public workshop is intended to provide information for and gain perspective from health care providers, other U.S. government agencies, public health organizations, academic experts, and industry on various aspects of the design of clinical trials evaluating new drugs to treat malaria. The input from this public workshop will also help in developing topics for future discussion.

Dates and Times: The public workshop will be held on June 30, 2016, from 8:30 a.m. to 4 p.m.

Location: The public workshop will be held at FDA's White Oak campus, 10903 New Hampshire Ave., Bldg. 31 Great Rm., Silver Spring, MD 20993. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.* Seating is limited and available only on a first-come, first-served basis.

Contact Persons: Ms. Lori Benner and/or Ms. Jessica Barnes, Center for Drug Evaluation and Research, Food and Drug Administration, Bldg. 22, Rm. 6221, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1300.

Registration: Registration is free for the public workshop. Interested parties are encouraged to register early. Seating will be available on a first-come, first-served basis. To register electronically, email registration information (including name, title, firm name, address, telephone, and fax number) to *Malariaworkshop2016@fda.hhs.gov.* Persons without access to the Internet can call 301–796–1300 to register. Persons needing a sign language interpreter or other special accommodations should notify Ms. Jessica Barnes or Ms. Lori Benner (see *Contact Persons*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: FDA is announcing a public workshop regarding scientific and regulatory considerations in the design of clinical trials of antimalarial drugs. Discussions will focus on developing two or more drugs used in combination, human challenge studies, issues/challenges associated with current detection methods, use of polymerase chain reaction, and other emerging rapid diagnostic tests in clinical trials.

The Agency encourages individuals, industry, health care professionals, researchers, public health organizations and other interested persons to attend this public workshop.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD. A transcript will also be available in either hard copy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, Rm. 6–30, Rockville, MD 20857. Transcripts will also be available on the Internet at *http://wcms.fda.gov/FDAgov/Drugs/NewsEvents/ucm490084.htm?SSContributor=true* approximately 45 days after the workshop.

Dated: May 4, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–10913 Filed 5–9–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–1210]

Technical Considerations for Additive Manufactured Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled "Technical Considerations for Additive Manufactured Devices." FDA has developed this draft leapfrog guidance to provide FDA's initial thoughts on technical considerations specific to devices using additive manufacturing, the broad category of manufacturing encompassing 3-dimensional (3D) printing. Specifically, this draft guidance outlines technical considerations associated with additive manufacturing processes, and testing and characterization for final finished devices fabricated using additive manufacturing. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by August 8, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of

Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2016–D–1210 for "Technical Considerations for Additive Manufactured Devices." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov*. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

An electronic copy of the draft guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance. Submit written requests for a single hard copy of the draft guidance document entitled "Technical Considerations for Additive Manufactured Devices" to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Matthew Di Prima, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 62, Rm. 2214, Silver Spring, MD 20993–0002, 301–796–2507; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has developed this draft leapfrog guidance to provide FDA's initial thoughts on technical considerations specific to devices using additive manufacturing (AM), the broad category of manufacturing encompassing 3D printing. In medical device applications, AM has the advantage of facilitating the creation of anatomically-matched devices and surgical instrumentation by using a patient's own medical imaging. Another advantage is the ease in fabricating complex geometric structures, allowing the creation of engineered open lattice structures, tortuous internal channels, and internal support structures that would not be easily possible using traditional (non-additive) manufacturing approaches. However, the unique aspects of the AM process, such as the layer-wise fabrication process, and the relative lack of medical device history of devices manufactured using AM techniques, pose challenges in determining optimal characterization and assessment methods for the final finished device, as well as optimal process validation and verification methods for these devices. To discuss these challenges and obtain initial stakeholder input, the FDA held a public workshop entitled "Additive Manufacturing of Medical Devices: An Interactive Discussion on the Technical Considerations of 3D Printing," on October 8–9, 2014 (*http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm397324.htm*). When finalized, this draft guidance document will recommend technical aspects of an additively manufactured device that should be considered through the phases of development, production process, process validation, and final finished device testing.

This draft guidance is a leapfrog guidance; leapfrog guidances are intended to serve as a mechanism by which the Agency can share initial thoughts regarding the content of premarket submissions for emerging technologies and new clinical applications that are likely to be of public health importance very early in product development. This leapfrog guidance represents the Agency's initial thinking, and our recommendations may change as more information becomes available. The Agency strongly encourages manufacturers to engage with CDRH and/or CBER through the Pre-Submission process to obtain more detailed feedback regarding their AM device or process. For more information on Pre-Submissions, please see "Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff" (*http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176.pdf*).

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on technical considerations for additive manufactured devices. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/*

DeviceRegulationandGuidance/GuidanceDocuments/default.htm. Guidance documents are also available at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm* or *http://www.regulations.gov.* Persons unable to download an electronic copy of "Technical Considerations for Additive Manufactured Devices" may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1400002 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 814, subparts B and E are approved under OMB control number 0910–0231; the collections of information in 21 CFR part 814, subpart H are approved under OMB control number 0910–0332; the collections of information in 21 CFR part 807, subpart E are approved under OMB control number 0910–0120; the collections of information in 21 CFR part 812 are approved under OMB control number 0910–0078; the collections of information in 21 CFR part 820 are approved under OMB control number 0910–0073; the collections of information in 21 CFR parts 801 and 809 are approved under OMB control number 0910–0485; and the collections of information in the guidance document entitled "Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff" are approved under OMB control number 0910–0756.

Dated: May 4, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–10924 Filed 5–9–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: HHS–OS–0990–New–30D]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, has submitted an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB) for review and approval. The ICR is for a new collection. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public on this ICR during the review and approval period.

Proposed Project: Million Hearts Social Network Analysis: Network Survey—OMB No. 0990–New—Office of the Assistant Secretary for Planning and Evaluation (ASPE).

Abstract: The Office of the Assistant Secretary for Planning and Evaluation (ASPE) is requesting approval on a new information collection request from the Office of Management and Budget (OMB) for purposes of conducting a study about the Million Hearts Initiative and its subsequent public-private partner network.

Million Hearts focuses on aligning the efforts of federal agencies, states, regions, health systems, communities and individuals towards this common goal, ensuring the coordination of public health, clinical care, and policy approaches to this complex problem. Previous research has shown that collaborative efforts among organizations with a variety of programming, resources and skill sets result in higher levels of community impact. Integrated efforts to address public health issues by involving multiple stakeholders are predicted to result in better health outcomes than programs that do not use a collaborative approach.

ASPE is requesting comment on the burden for this study that is examining the Million Hearts public-private partnership network. The goal of developing this activity is to examine the network to identify facilitators and barriers to effective communication and collaboration in addressing large and complex public health problems like cardiovascular disease. This project wants to take the lessons learned from this unique and massive collaboration and apply them to other efforts to improve the health and well-being of Americans.

DATES: Comments on the ICR must be received on or before June 9, 2016.

ADDRESSES: Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, *Information.CollectionClearance@hhs.gov* or (202) 690–6162.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the Information Collection Request Title and document identifier HHS–OS–0990–New–30D for reference.

Information Collection Request Title:

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Million Hearts Network Survey	100	1	30/60	50
Total				50

Darius Taylor,

Information Collection Clearance Officer.

[FR Doc. 2016–10953 Filed 5–9–16; 8:45 am]

BILLING CODE 4150–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; Asymmetric Hearing Loss Clinical Trial Review.

Date: June 1, 2016.

Time: 2:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Kausik Ray, Ph.D., Scientific Review Officer, National Institute on Deafness and Other Communication Disorders, National Institutes of Health Rockville, MD 20850, 301–402–3587, *rayk@nidcd.nih.gov.*

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; VSL Fellowships Review.

Date: June 14, 2016

Time: 11:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Shiguang Yang, DVM, Ph.D., Scientific Review Officer, Division of Extramural Activities, NIDCD, NIH, 6001 Executive Blvd., Room 8349, Bethesda, MD 20892, 301–496–8683, *yangshi@nidcd.nih.gov.*

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; Hearing and Balance Fellowships Review.

Date: June 15, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

Contact Person: Sheo Singh, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, 6001 Executive Blvd., Room 8351, Bethesda, MD 20892, 301–496–8683, *singhs@nidcd.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: May 4, 2016.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–10882 Filed 5–9–16; 8:45 am]

BILLING CODE 4140–01–P

Department of Health and Human Services

National Institutes of Health

Office of the Director; Notice of Meeting

Notice is hereby given of a meeting scheduled by the Deputy Director for Intramural Research at the National Institutes of Health (NIH) with the Chairpersons of the Boards of Scientific Counselors. The Boards of Scientific Counselors are advisory groups to the Scientific Directors of the Intramural Research Programs at the NIH.

The meeting will be open to the public. Attendance in person is limited to space available in the conference room. Individuals who wish to listen to the discussions by telephone must call using the information listed below. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the contact person listed below.

Date: Friday, June 17, 2016.

Time: 10:00 a.m. to 2:00 p.m. EST.

Place: Room 7, C–Wing, 6th Floor, Building 31, 31 Center Drive, Bethesda, MD 20892.

Teleconference Information: 888–849–8917. Participant Passcode 48961.

Agenda: The meeting will include a discussion of policies and procedures that apply to the regular review of NIH intramural scientists and their work.

Contact Person: Margaret McBurney, Program Specialist, Office of the Deputy Director for Intramural Research, 1 Center Drive, Room 160, Bethesda, MD 20892, email: *mmcburney@od.nih.gov,* Phone: 301–496–1921, Fax: 301–402–4273.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Dated: May 4, 2016.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–10884 Filed 5–9–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Human Genome Research Institute Special Emphasis Panel; GNOM–R–13 SEP.

Date: June 2–3, 2016.

Time: 4:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: NHGRI, 5635FL, 3rd Floor Conference Room, Fishers Lane, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Keith McKenney, Ph.D., Scientific Review Officer, NHGRI, 5635 Fishers Lane, Suite 4076, Bethesda, MD 20814, 301–594–4280, *mckenneyk@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: *May 4, 2016.*

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–10879 Filed 5–9–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Human Genome Research Institute Initial Review Group; Genome Research Review Committee.

Date: June 2, 2016.

Time: 11:30 a.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: NHGRI, 5635FL, 3rd Floor Conference Room 3146, Fishers Lane, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Keith McKenney, Ph.D., Scientific Review Officer, NHGRI, 5635 Fishers Lane, Suite 4076, MSC 9306, Bethesda, MD 20814, 301–594–4280, *mckenneyk@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: May 4, 2016.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–10878 Filed 5–9–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Heart, Lung, and Blood Advisory Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Advisory Council.

Date: June 15, 2016.

Open: 8:00 a.m. to 12:30 p.m.

Agenda: To discuss program policies and issues.

Place: National Institutes of Health, Porter Neuroscience Research Center, Building 35A, Convent Drive, Bethesda, MD 20892.

Closed: 1:30 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Porter Neuroscience Research Center, Building 35A, Convent Drive, Bethesda, MD 20892.

Contact Person: Jodi Black, Ph.D., Acting Director, Division of Extramural Research Activities, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Room 7104, Bethesda, MD 20892, (301) 435–0260, *blackj@nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *www.nhlbi.nih.gov/meetings/nhlbac/index.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: May 4, 2016.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–10880 Filed 5–9–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Advisory Child Health and Human Development Council, June 9, 2016, 8:00 a.m. to June 9, 2016, Adjournment, National Institutes of Health, Building 31, C Wing, Conference Room 10, 9000 Rockville Pike, Bethesda, MD 20892 which was published in the **Federal Register** on April 25, 2016, 81 FR 2411.

This meeting notice is amended to change the conference room location from Room 6 to Room 10. The meeting is partially closed to the public.

Dated: May 4, 2016.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–10881 Filed 5–9–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; NIH Office of Intramural Training & Education Application (OD)

SUMMARY: Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on November 10, 2015, page 69685 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The Office of the Director (OD), NIH, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: NIH Desk Officer.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: Dr. Patricia Wagner, Office of Intramural Training & Education (OITE), 2 Center Drive; Building 2/Room 2E06; Bethesda, Maryland 20892, or call non-toll-free number 240–476–3619, or Email your request, including your address to: *wagnerpa@od.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: NIH Office of Intramural Training & Education Application, Revision, 0925–0299 Expiration Date: 3/31/2016, Office of Intramural Training & Education (OITE), Office of the Director (OD), National Institutes of Health (NIH).

The Office of Intramural Training & Education (OITE) administers a variety of programs and initiatives to recruit pre-college through pre-doctoral educational level individuals into the National Institutes of Health Intramural Research Program (NIH–IRP) to facilitate their development into future biomedical scientists. The proposed information collection is necessary in order to determine the eligibility and quality of potential awardees for traineeships in these programs. The applications for admission consideration include key areas such as: Personal information, ability to meet eligibility criteria, contact information, university assigned student identification number, training program selection, scientific discipline interests, educational history, standardized examination scores, reference information, resume components, employment history, employment interests, dissertation research details, letters of recommendation, financial aid history, sensitive data, travel information, as well as feedback questions about interviews and application submission experiences. Sensitive data collected on the applicants: Race, gender, ethnicity, relatives at the NIH, and recruitment method, are made available only to OITE staff members or in aggregate form to select NIH offices and are not used by the admission committees for admission consideration.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 16,332.55.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Number of respondents	Number of responses annually per respondent	Total annual burden hours	Total annual burden hours
Summer Internship Program—Application	7,525	1	1	7,525
Amgen Scholars at NIH Program—Supplemental Application	300	1	3/60	15
High School Scientific Training & Enrichment Program—Contact Information	40	1	3/60	2
NIH Visit Week—Application	30	1	1	30
Undergraduate Scholarship Program (UGSP)—Application	150	1	1	150
Undergraduate Scholarship Program—Certificate of Exceptional Financial Need (Completed by Applicant)	300	1	3/60	15
Undergraduate Scholarship Program—Certificate of Exceptional Financial Need (Completed by University Staff)	300	1	15/60	75
Undergraduate Scholarship Program (UGSP)—Renewal Application	15	1	1	15
Undergraduate Scholarship Program—Deferment Form (Completed by UGSP Scholar)	40	1	3/60	2
Undergraduate Scholarship Program—Deferment Form (Completed by University Staff)	40	1	15/60	10
Undergraduate Scholarship Program—Scholar Contract	30	1	10/60	5
Undergraduate Scholarship Program—Evaluation of Scholar PayBack Period	50	1	15/60	13
Postbaccalaureate/Technical Training Program—Application	2,050	1	1	2,050
NIH Academy Training Program—Supplemental Application	225	1	1	225
Graduate Partnerships Program—Application	275	1	1	275
Graduate Partnerships Program—Registration	150	1	1	150
Graduate Partnerships Program—Interview Experience Survey (60% Response Rate)	30	1	10/60	5
Evaluation—Recommendation Letters for Prospective Students	22,570	1	15/60	5,643
Survey—Optional Statistics (Majority of Programs; 25% Response Rate)	2,571	1	3/60	129
Totals	36,691	36,691	N/A	16,334

Dated: May 3, 2016.

Lawrence A. Tabak,

Deputy Director, National Institutes of Health.

[FR Doc. 2016–10994 Filed 5–9–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App), notice is hereby given of the meetings.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable materials, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Library of Medicine Special Emphasis Panel; T15 Review.

Date: August 3, 2016.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Suites Marriott, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Arthur A. Petrosian, Ph.D., Chief Scientific Review Officer, Division of Extramural Programs, National Library of Medicine, 6705 Rockledge Drive, Suite 301, Bethesda, MD 20892–7968, 301–496–4253, *petrosia@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program No. 93.879, Medical Library Assistance, National Institutes of Health, HHS)

Dated: May 4, 2016.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–10883 Filed 5–9–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs And Border Protection

Accreditation and Approval of Quality Custom Inspections and Laboratories, LLC, as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Quality Custom Inspections and Laboratories, LLC, as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that Quality Custom Inspections and Laboratories, LLC, has been approved to gauge and accredited to test petroleum and petroleum products for customs purposes for the next three years as of October 20, 2015.

DATES: *Effective Dates:* The accreditation and approval of Quality Custom Inspections and Laboratories, LLC, as commercial gauger and laboratory became effective on October 20, 2015. The next triennial inspection date will be scheduled for October 2018.

FOR FURTHER INFORMATION CONTACT: Approved Gauger and Accredited Laboratories Manager, Laboratories and Scientific Services Directorate, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW., Suite 1500N, Washington, DC 20229, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, that Quality Custom Inspections and Laboratories, LLC, 402 Pasadena Blvd., Pasadena, TX 77506, has been approved to gauge and accredited to test petroleum and petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Quality Custom Inspections and Laboratories, LLC, is approved for the following gauging procedures for petroleum and certain petroleum products set forth by the American Petroleum Institute (API):

API chapters	Title
3	Tank gauging.
7	Temperature Determination.
8	Sampling.
11	Physical property.
12	Calculations.
17	Maritime Measurements.

Quality Custom Inspections and Laboratories, LLC, is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM	Title
27–01	ASTM D–287	Standard test method for API Gravity of crude petroleum products and petroleum products (Hydrometer Method).
27–03	ASTM D–4006	Standard test method for water in crude oil by distillation.
27–04	ASTM D–95	Standard test method for water in petroleum products and bituminous materials by distillation.
27–06	ASTM D–473	Standard test method for sediment in crude oils and fuel oils by the extraction method.
27–08	ASTM D–86	Standard Test Method for Distillation of Petroleum Products.
27–11	ASTM D–445	Standard Test Method for Kinematic Viscosity of Transparent and Opaque Liquids (the Calculation of Dynamic Velocity).
27–14	ASTM D–2622	Standard test method for Sulfur in Petroleum Products (X-Ray spectrographic methods).
27–46	ASTM D–5002	Standard Test Method for Density and Relative Density of Crude Oils by Digital Density Analyzer.
27–48	ASTM D–4052	Standard test method for density and relative density of liquids by digital density meter.
27–50	ASTM D–50	Standard test methods for flash point by Pensky-Martens Closed Cup Tester.
27–53	ASTM D–2709	Standard test method for water and sediment in middle distillate by the centrifuge method.
27–58	ASTM D–5191	Standard Test Method For Vapor Pressure of Petroleum Products (Mini Method).

Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov.* Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories.

http://www.cbp.gov/about/labs-scientific/commercial-gaugers-and-laboratories.

Dated: May 2, 2016.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services Directorate.

[FR Doc. 2016–10971 Filed 5–9–16; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Approval of Intertek USA, Inc., as a Commercial Gauger

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of approval of Intertek USA, Inc., as a commercial gauger.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that Intertek USA, Inc., has been approved to gauge petroleum and petroleum products for customs purposes for the next three years as of August 25, 2015.

DATES: *Effective Dates:* The approval of Intertek USA, Inc., as commercial gauger became effective on August 25, 2015. The next triennial inspection date will be scheduled for August 2018.

FOR FURTHER INFORMATION CONTACT: Approved Gauger and Accredited Laboratories Manager, Laboratories and Scientific Services Directorate, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW., Suite 1500N, Washington, DC 20229, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.13, that Intertek USA, Inc., 354 Fairbanks Dr., Valdez, AK 99686, has been approved to gauge petroleum and petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.13. Intertek USA, Inc., is approved for the following gauging procedures for petroleum and certain petroleum products set forth by the American Petroleum Institute (API):

API chapters	Title
3	Tank gauging.
7	Temperature Determination.
8	Sampling.
12	Calculations.
17	Maritime Measurements.

Anyone wishing to employ this entity to conduct gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific gauger service requested. Alternatively, inquiries regarding the specific gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov.* Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://www.cbp.gov/about/labs-scientific/commercial-gaugers-and-laboratories*

Dated: May 2, 2016.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services Directorate.

[FR Doc. 2016–10972 Filed 5–9–16; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation of R. Markey & Sons, Inc., Markan Laboratories, as a Commercial Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation of R. Markey & Sons, Inc., Markan Laboratories, as a commercial laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that R. Markey & Sons, Inc., Markan Laboratories, has been accredited to test certain sugar products for customs purposes for the next three years as of June 23, 2015.

DATES: *Effective Dates:* The accreditation of R. Markey & Sons, Inc., Markan Laboratories, as commercial laboratory became effective on June 23, 2015. The next triennial inspection date will be scheduled for June 2018.

FOR FURTHER INFORMATION CONTACT: Approved Gauger and Accredited Laboratories Manager, Laboratories and Scientific Services Directorate, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW., Suite 1500N, Washington, DC 20229, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12, that R. Markey & Sons, Inc., Markan Laboratories, 5 Hanover Square, 12th Floor, New York, NY 10004, has been accredited to test certain sugar products for customs purposes, in accordance with the provisions of 19 CFR 151.12. R. Markey & Sons, Inc., Markan Laboratories, is accredited for the following laboratory analysis procedures and methods for sugar products set forth by the Commodity Group Brochures, the U.S. Customs and Border Protection Laboratory Methods (CBPL) and International Commission for Uniform Methods of Sugar Analysis (ICUMSA):

CBPL No.	ICUMSA	Title
17–01	GS 1/2/3–1	Polarisation of Raw Sugar.
17–02	GS 2/3–1	The Braunschweig Method for the Polarisation of White Sugar by Polarimetry.
17–07	GS 2/1/3–15	Sugar Moisture by Loss on Drying.
17–20	GS 1/2/3–2	The Determination of the Polarisation of Raw Sugar without Wet Lead Clarification.

Anyone wishing to employ this entity to conduct laboratory analyses should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test service requested. Alternatively, inquiries regarding the specific test service this entity is accredited to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov.* Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://www.cbp.gov/about/labs-scientific/commercial-gaugers-and-laboratories.*

Dated: May 2, 2016.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services Directorate.

[FR Doc. 2016–10974 Filed 5–9–16; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of SGS North America, Inc., as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of SGS North America, Inc., as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that SGS North America, Inc., has been approved to gauge and accredited to test petroleum and petroleum products for customs purposes for the next three years as of June 24, 2015.

DATES: *Effective Dates:* The accreditation and approval of SGS North America, Inc., as commercial gauger and laboratory became effective on June 24, 2015. The next triennial inspection date will be scheduled for June 2018.

FOR FURTHER INFORMATION CONTACT: Approved Gauger and Accredited Laboratories Manager, Laboratories and Scientific Services Directorate, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW., Suite 1500N, Washington, DC 20229, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, that SGS North America, Inc., 614 Heron Drive, Bridgeport, NJ 08014, has been approved to gauge and accredited to test petroleum and petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. SGS North America, Inc., is approved for the following gauging procedures for petroleum and certain petroleum products set forth by the American Petroleum Institute (API):

API chapters	Title
1	Vocabulary.
3	Tank gauging.
7	Temperature Determination.
8	Sampling.
9	Density Determination.
12	Calculations.
17	Maritime Measurements.

SGS North America, Inc., is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM	Title
27–07	ASTM D–4807	Standard Test Method for Sediment in Crude Oil by Membrane Filtration.
27–13	ASTM D–4294	Standard test method for sulfur in petroleum and petroleum products by energy-dispersive x-ray fluorescence spectrometry.
27–46	ASTM D–5002	Standard Test Method for Density and Relative Density of Crude Oils by Digital Density Analyzer.
N/A	ASTM D–4377	Standard Test Method for Water in Crude Oils by Potentiometric Karl Fischer Titration.

Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov.* Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://www.cbp.gov/about/labs-scientific/commercial-gaugers-and-laboratories.*

Dated: May 2, 2016.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services Directorate.

[FR Doc. 2016–10973 Filed 5–9–16; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0033]

Agency Information Collection Activities: Report of Medical Examination and Vaccination Record, Form I–693; Revision of a Currently Approved Collection

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 60-Day Notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) invites the general public and other Federal agencies to comment upon this proposed revision of a currently approved collection of information. In accordance with the Paperwork Reduction Act (PRA) of 1995, the information collection notice is published in the **Federal Register** to obtain comments regarding the nature of the information collection, the categories of respondents, the estimated burden (*i.e.* the time, effort, and resources used by the respondents to respond), the estimated cost to the respondent, and the actual information collection instruments.

DATES: Comments are encouraged and will be accepted for 60 days until July 11, 2016.

ADDRESSES: All submissions received must include the OMB Control Number 1615–0033 in the subject box, the agency name and Docket ID USCIS–2006–0074. To avoid duplicate submissions, please use only *one* of the following methods to submit comments:

(1) *Online.* Submit comments via the Federal eRulemaking Portal Web site at *http://www.regulations.gov* under e-Docket ID number USCIS–2006–0074;

(2) *Email.* Submit comments to *USCISFRComment@uscis.dhs.gov;*

(3) *Mail.* Submit written comments to DHS, USCIS, Office of Policy and Strategy, Chief, Regulatory Coordination Division, 20 Massachusetts Avenue NW., Washington, DC 20529–2140.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Acting Chief, 20 Massachusetts Avenue NW., Washington, DC 20529–2140, Telephone number (202) 272–8377 (This is not a toll-free number. Comments are not accepted via telephone message). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS Web site at *http://www.uscis.gov,* or call the USCIS National Customer Service Center at (800) 375–5283; TTY (800) 767–1833.

SUPPLEMENTARY INFORMATION:

Comments

You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: *http://www.regulations.gov* and enter USCIS–2006–0074 in the search box. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.*

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Report of Medical Examination and Vaccination Record.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* I–693, USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. Form I–693 is necessary for USCIS to determine the eligibility of an applicant for lawful permanent resident status, creating a potential public health risk or denying the applicant an immigration benefit to which he or she may be legally entitled.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection I–693 is 574,000 and the estimated hour burden per response is 2.5 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 1,435,000 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $283,412,500.

Dated: May 4, 2016.

Samantha Deshommes,

Acting Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2016–10851 Filed 5–9–16; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R4–ES–2016–N031; FF04E00000–167–FXES11150400000]

Department of Defense; Proposed Gopher Tortoise Conservation and Crediting Strategy

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comment.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce the availability for comment of a proposed "Gopher Tortoise Conservation and Crediting Strategy" to be implemented in Alabama, Georgia, Florida, and South Carolina, where the gopher tortoise occurs but is unlisted.

DATES: We must receive any written comments at our Regional Office (see **ADDRESSES**) on or before June 9, 2016.

ADDRESSES: To request further information, review documents, or submit written comments, please use the following methods and specify that your information request or comments are in reference to the "DOD Gopher Tortoise Conservation and Crediting Strategy."

- *Internet:* Documents may be viewed and downloaded on the Internet at *http://www.fws.gov/southeast/candidateconservation/examples.html.*
- *Email: michael_harris@fws.gov.* Include "DOD Gopher Tortoise Conservation and Crediting Strategy" in the subject line of your message.
- *U.S. Mail:* Mr. Michael Harris, At-Risk Species Coordinator, Fish and Wildlife Service, Southeast Regional Office, 1875 Century Boulevard, Atlanta, GA 30345.
- *In-Person Drop-off, Viewing, or Pickup:* Call 404–679–7066 to make an appointment (necessary for viewing or pickup only) during regular business hours at the Fish and Wildlife Service's Regional Office, 1875 Century Boulevard, Suite 200, Atlanta, GA 30345. Written comments can be dropped off during regular business hours at the above address on or before the closing date of the public comment period (see **DATES**). Note that requests for any documents must be in writing to be processed.

FOR FURTHER INFORMATION CONTACT: Mr. Michael Harris, At-Risk Species Coordinator, at the Regional Office (see **ADDRESSES**), telephone: 404–679–7066. If you use a telecommunications device for the deaf (TDD), please call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Introduction

We announce the availability for comment of a proposed "Gopher Tortoise Conservation and Crediting Strategy" (Strategy) for implementation in Alabama, Georgia, Florida, and South Carolina (Strategy Area), where the gopher tortoise (*Gopherus Polyphemus*) occurs but is unlisted. The Strategy Area is within the historic range of the species. The Strategy would enable the military services of the Department of Defense to generate conservation credits to be used to offset impacts to the gopher tortoise from military training and operations if the species were to be listed as "threatened" or "endangered" under the Endangered Species Act of 1973, as amended (Act), in the future.

Strategy

The Strategy was developed by the Service in conjunction with the following State wildlife agencies: Wildlife and Freshwater Fisheries Division of the Alabama Department of Conservation and Natural Resources; Florida Fish and Wildlife Conservation Commission; Wildlife Resources Division of the Georgia Department of Natural Resources; and, the South Carolina Department of Natural Resources. The Strategy describes conservation activities designed to protect and enhance habitats for the gopher tortoise on lands that have been permanently protected in the Strategy Area. The focus of the conservation activities would be the areas where significant gopher tortoise populations, as identified through population and habitat analyses conducted by the Service and the State wildlife agencies, could be conserved.

Under the Strategy, the military services would voluntarily agree to undertake specified conservation activities to conserve gopher tortoise populations and habitat within the Strategy Area. The suite of conservation activities that could be performed includes land acquisition for the permanent protection of populations of the species; enhancement, restoration, or maintenance of the species' habitat via prescribed fire and thinning to maintain forest habitats and control of invasive exotic species; and/or, translocation of gopher tortoises to augment existing populations in permanently protected conservation areas within the Strategy Area.

The military services could generate and accumulate Gopher Tortoise Conservation Credits (GTCCs) for undertaking the conservation activities set forth in the Strategy. Those GTCCs could, in turn, be tendered to the Service to offset impacts to the species from training operations were the gopher tortoise to be federally-listed as "threatened" or "endangered" in the portion of the Strategy Area where the impacts occurred. Pursuant to 50 CFR 402.14 (g)(8), during formal consultation under section 7 of the Act, the Service must "give appropriate consideration to any beneficial actions taken by the Federal agency or applicant, including any actions taken prior to the initiation of consultation."

We specifically request information, views, and opinions from the public via this notice on the proposed Strategy. We will evaluate the Strategy under section 7 of the Act as a programmatic action as defined in 50 CFR 402.02. As a framework programmatic action, we have determined that the Strategy qualifies for categorical exclusion under the National Environmental Policy Act (NEPA) in accordance with the Department of the Interior's NEPA implementing regulations in Part 46 of Title 43 of the Code of Federal Regulations (43 CFR sections 46.205, 46.210, and 46.215). We will conduct independent NEPA evaluations of each project undertaken by the military services under this Strategy as such is proposed.

Public Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Next Steps

Prior to making a final decision on whether to approve the Strategy, we will evaluate the Strategy and fully consider all comments received during the 30-day comment period. We also will conduct an intra-Service section 7 consultation to determine whether the Strategy meets the requirements of section 7 of the Act. If we determine that the requirements are met, we will approve and adopt the Strategy for implementation in accordance with the applicable regulatory requirements, including 50 CFR 402.14(g)(8).

Authority

We provide this notice under section 7 of the Act (16 U.S.C. 1531 *et seq.*) and NEPA regulations (40 CFR 1506.6).

Dated: April 20, 2016.

Mike Oetker,

Deputy Regional Director.

[FR Doc. 2016–10939 Filed 5–9–16; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

[RR04084000, XXXR4081X1, RN.20350010.REG0000]

Colorado River Basin Salinity Control Advisory Council Notice of Public Meeting

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of public meeting.

SUMMARY: The Colorado River Basin Salinity Control Advisory Council (Council) was established by the Colorado River Basin Salinity Control Act of 1974 (Pub. L. 93–320) (Act) to receive reports and advise Federal agencies on implementing the Act. In accordance with the Federal Advisory Committee Act, the Bureau of Reclamation announces that the Council will meet as detailed below. The meeting of the Council is open to the public.

DATES: The Council will convene the meeting on Wednesday, June 8, 2016, at 1:00 p.m. and adjourn at approximately 5:00 p.m. The Council will reconvene the meeting on Thursday, June 9, 2016, at 8:30 a.m. and adjourn the meeting at approximately 11:00 a.m.

ADDRESSES: The meeting will be held at the Castle Peak Room—Keystone Conference Center, 21966 Highway 6, Keystone, Colorado. Send written comments to Mr. Kib Jacobson, Bureau of Reclamation, Upper Colorado Regional Office, 125 South State Street, Room 8100, Salt Lake City, Utah 84138–1147; telephone (801) 524–3753; facsimile (801) 524–3847; email at: *kjacobson@usbr.gov.*

FOR FURTHER INFORMATION CONTACT: Kib Jacobson, telephone (801) 524–3753; facsimile (801) 524–3847; email at: *kjacobson@usbr.gov.*

SUPPLEMENTARY INFORMATION: Any member of the public may file written statements with the Council before, during, or up to 30 days after the meeting either in person or by mail. To the extent that time permits, the Council chairman will allow public presentation of oral comments at the meeting. To allow full consideration of information by Council members, written notice must be provided at least 5 days prior to the meeting. Any written comments received prior to the meeting will be provided to Council members at the meeting.

The purpose of the meeting is to discuss and take appropriate actions regarding the following: (1) The Basin States Program created by Public Law

110–246, which amended the Act; (2) responses to the Advisory Council Report; and (3) other items within the jurisdiction of the Council.

Public Disclosure

Before including your address, phone number, email address, or other personal identifying information in your comment, please be advised that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: April 4, 2016.

Shelly Wiser,

Acting Regional Director, Upper Colorado Region.

[FR Doc. 2016–10202 Filed 5–9–16; 8:45 am]

BILLING CODE 4332–90–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed First Amended Consent Decree Under the Clean Water Act

On May 2, 2016, the Department of Justice lodged a proposed First Amended Consent Decree with the United States District Court for the Northern District of Ohio in the lawsuit entitled *United States* v. *City of Akron, Ohio, et al.,* Civil Action No. 09–cv–00272.

In this action the United States, and the State of Ohio in a cross-claim, sought civil penalties and injunctive relief for violations of the Clean Water Act, 33 U.S.C. 1251 *et seq.,* in connection with the City of Akron's ("Akron's" or "City's") operation of its municipal wastewater treatment facility and sewer system. Under the Consent Decree, which was approved by the Court in January 2014, Akron was required to develop and implement a comprehensive plan to address overflows from its combined sewer system and bypasses around secondary treatment at the wastewater treatment facility. That plan, known as the "Long Term Control Plan Update" ("LTCP Update"), which was approved by the United States in November 2011 and the State of Ohio in April 2012, sets forth specific projects that the City is required to implement, and identifies dates for completion of these projects.

The proposed amendment modifies two provisions of the 2014 Consent Decree to take into account new engineering solutions. Both of the affected projects are included in the approved LTCP Update. The first modification requires that the City expand secondary treatment at its wastewater treatment plant sooner than is required under the current agreement: Under the amended Decree, the City will achieve 220 million gallons/day of secondary treatment capacity by 2019 instead of 2021. In exchange, the City may delay by approximately two years the installation of a biologically enhanced high rate treatment ("BioActiflo") unit at the treatment plant. The City has committed to, and the United States previously approved (under the terms of the Consent Decree itself), an increase in the size of secondary treatment capacity, and an equivalent reduction in the size of the BioActiflo unit.

The second modification eliminates the requirement for the City to construct a mile-and-a-half-long sewer line parallel to an existing interceptor that connects the combined sewer system to the wastewater treatment plant. In place of the parallel sewer, the amendment requires the City to construct a steel reinforced concrete cap along all but a fraction of the existing interceptor sewer line. The cap will be in place by November 2017, the same Achievement of Full Operation date as for the original project.

The publication of this notice opens a period for public comment on the First Amended Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States* v. *City of Akron, Ohio, et al.,* D.J. Ref. No. 90–5–1–1–3144/2. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the First Amendment to the Consent Decree may be examined and downloaded at this Justice Department Web site: *https://www.justice.gov/enrd/consent-decrees.* We will provide a paper copy of the proposed amendment to the Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $7.25 (25 cents per page reproduction cost) payable to the United States Treasury.

Randall M. Stone,

Acting Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2016–10954 Filed 5–9–16; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

[OMB Number 1105–0099]

United States Marshals Service; Agency Information Collection Activities; Proposed Collection Comments Requested; Extension With Change, of a Previously Approved Collection USMS Medical Forms

AGENCY: U.S. Marshals Service, Department of Justice.

ACTION: 60-day notice.

SUMMARY: The Department of Justice (DOJ), U.S. Marshals Service, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until July 11, 2016.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Nicole Timmons, U.S. Marshals Service, Washington, DC 20530–0001 (phone: 202–307–5168).

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- —Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the U.S. Marshals Service, including whether the information will have practical utility;
- —Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the

methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection:* Extension of a currently approved collection.

2. *The Title of the Form/Collection:* USMS Medical Forms

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form Numbers:

—USM–522A Physician Evaluation Report for USMS Operational Employees

—USM–522P Physician Evaluation Report for USMS Operational Employees—Pregnancy Only

—USM–600 Physical Requirements of USMS District Security Officers

—CSO–012 Request to Reevaluate Court Security Officer's Medical Qualification

Component for all above-listed forms: U.S. Marshals Service.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

—USM–522A Physician Evaluation Report for USMS Operational Employees

○ Affected public: Private sector (Physicians)

○ Brief abstract: This form is completed by an USMS operational employee's treating physician to report any illness/injury (other than pregnancy) that requires restriction from full performance of duties for longer than 80 consecutive hours.

—USM–522P Physician Evaluation Report for USMS Operational Employees (Pregnancy Only)

○ Affected public: Private sector (Physicians)

○ Brief abstract: Form USM–522P must be completed by the OB/GYN physician of pregnant USMS operational employees to specify any restrictions from full performance of duties.

—USM–600 Physical Requirements of USMS District Security Officers

Affected public: Private sector (Physicians)

○ Brief abstract: It is the policy of the USMS to ensure a law enforcement work force that is medically able to safely perform therequired job functions. All applicants for law enforcement positions must have pre-employment physical examinations; existing District Security Officers (DSOs) must recertify that they are physically fit to perform the duties of their position each year. DSOs are individual contractors, not employees of USMS; Form USM–522 does not apply to DSOs.

—CSO–012 Request to Reevaluate Court Security Officer's Qualification

○ Affected public: Private sector (Physicians)

○ Brief abstract: This form is completed by the Court Security Officer (CSO)'s attending physician to determine whether a CSO is physically able to return to work after an injury, serious illness, or surgery. The physician returns the evaluation to the contracting company, and if the determination is that the CSO may return to work, the CSO–012 is then signed off on by the contracting company and forwarded to the USMS for final review by USMS' designated medical reviewing official. Court Security Officers are contractors, not employees of USMS; Form USM–522A does not apply to CSOs.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:*

—USM–522A Physician Evaluation Report for USMS Operational Employees

It is estimated that 208 respondents will complete a 20 minute form twice per year.

—USM–522P Physician Evaluation Report for USMS Operational Employees (Pregnancy Only)

It is estimated that 7 respondents will complete a 15 minute form twice per year.

—USM–600 Physical Requirements of USMS District Security Officers

It is estimated that 2,000 respondents will complete a 20 minute form.

—CSO–012 Request to Reevaluate Court Security Officer's Medical Qualification

It is estimated that 300 respondents will complete a 30 minute form.

6. *An estimate of the total public burden (in hours) associated with the collection:*

—USM–522A Physician Evaluation Report for USMS Operational Employees

There are an estimated 139 annual total burden hours associated with this collection.

—USM–522P Physician Evaluation Report for USMS Operational Employees (Pregnancy Only)

There are an estimated 4 annual total burden hours associated with this collection.

—USM–600 Physical Requirements of USMS District Security Officers

There are an estimated 667 annual total burden hours associated with this collection.

—CSO–012 Request to Reevaluate Court Security Officer's Medical Qualification

There are an estimated 150 annual total burden hours associated with this collection.

Total Annual Time Burden (Hr): 960.

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., 3E.405B, Washington, DC 20530.

Dated: May 5, 2016.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2016–10936 Filed 5–9–16; 8:45 am]

BILLING CODE 4410–04–P

DEPARTMENT OF JUSTICE

Notice of Filing of Proposed Settlement Agreement Regarding Environmental Claims in Connection With Army Creek Landfill Site, Blosenski Landfill Site and Delaware Sand and Gravel Site

On May 3, 2016, a proposed Settlement Agreement Regarding Environmental Claims in Connection with Army Creek Landfill Site, Blosenski Landfill Site and Delaware Sand and Gravel Site was filed in the United States Bankruptcy Court for the Northern District of Illinois, in the proceeding entitled *In re Budd Company, Inc.*, Ch. 11, Bankr. No. 14–11873–JBS.

Under the proposed Settlement Agreement, the debtor, Budd Company, Inc. ("Budd") will agree to allowed general unsecured claims of (1) $100,000 for response costs incurred and to be incurred at the Army Creek Landfill Site near New Castle, Delaware;

(2) $1,847,557 for response costs at the Blosenski Landfill Site in West Caln Township, Pennsylvania ($590,321 allocated to EPA, and the remainder to a group of other responsible parties); and (3) $4,250,000 for response costs at the Delaware Sand & Gravel Quarry and Landfill Site near New Castle Delaware ($3,850,806 allocated to EPA, the rest to a group of other responsible parties). Under Budd's proposed Plan of Reorganization, it is anticipated that allowed general unsecured claims will be paid at a rate of 66%.

The publication of this notice opens a period for public comment on the Settlement Agreement. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *In re Budd Company, Inc.*, D.J. Ref. No. 90–11–2–556/1. All comments must be submitted no later than midnight (Eastern Time) May 25, 2016. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the Settlement Agreement may be examined and downloaded at this Justice Department Web site: *https://www.justice.gov/enrd/consent-decrees.* We will provide a paper copy of the Settlement Agreement upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $ 5.50 (25 cents per page reproduction cost) payable to the United States Treasury.

Jeffrey K. Sands,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2016–10955 Filed 5–9–16; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Standard on 4,4′-Methylenedianiline in Construction

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Occupational Safety and Health Administration (OSHA) sponsored information collection request (ICR) titled, "Standard on 4,4′-Methylenedianiline in Construction," to the Office of Management and Budget (OMB) for review and approval for continued use, without change, in accordance with the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.* Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before June 9, 2016.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201602-1218-003* (this link will only become active on the day following publication of this notice) or by contacting Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail or courier to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–OSHA, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503; by Fax: 202–395–5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW., Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Contact Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Authority: 44 U.S.C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: This ICR seeks to extend PRA authority for the Standard on 4,4′-Methylenedianiline (MDA) in Construction information collection requirements codified in regulations 29 CFR 1926.60. The Standard protects workers from adverse health effects associated with occupational exposure to MDA in the construction industry. An Occupational Safety and Health Act (OSH Act) covered employer subject to the Standard must monitor worker exposure and ensure exposures are within the permissible limits, provide workers with medical examinations and training, and establish and maintain worker exposure-monitoring and medical records. OSH Act sections 2(b)(9), 6, and 8(c) authorize this information collection. *See* 29 U.S.C. 651(b)(9), 655, and 657(c).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1218–0183.

OMB authorization for an ICR cannot be for more than three (3) years without renewal, and the current approval for this collection is scheduled to expire on May 31, 2015. The DOL seeks to extend PRA authorization for this information collection for three (3) more years, without any change to existing requirements. The DOL notes that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on December 17, 2015 (80 FR 78773).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within thirty (30) days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1218–0183. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Agency: DOL–OSHA.

Title of Collection: Standard on 4,4′-Methylenedianiline in Construction.

OMB Control Number: 1218–0183.

Affected Public: Private Sector—business or other for-profits.

Total Estimated Number of Respondents: 330.

Total Estimated Number of Responses: 2,469.

Total Estimated Annual Time Burden: 986 hours.

Total Estimated Annual Other Costs Burden: $74,466.

Dated: May 5, 2016.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2016–10966 Filed 5–9–16; 8:45 am]

BILLING CODE 4510–26–P

LEGAL SERVICES CORPORATION

Sunshine Act Meeting

SUMMARY: Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, that the Operations and Regulations Committee (Committee) of the Board of Directors for the Legal Services Corporation (LSC) will hold its second Rulemaking Workshop (Workshop) to solicit public input on revisions to LSC's Cost Standards and Procedures and the Property Acquisition and Management Manual (PAMM).

DATE AND TIME: Wednesday, May 18, 2016, 1:30–4:30 p.m. EDT.

LOCATION: F. William McCalpin Conference Center, Legal Services Corporation Headquarters, 3333 K Street NW., 3rd Floor, Washington DC 20007.

PUBLIC OBSERVATION AND PARTICIPATION: LSC encourages observation of and participation in the Workshop by interested individuals and organizations. The Workshop will be entirely open to public observation and will include opportunities for individuals who are not members of the panel to participate in person or via telephone. Persons interested in speaking during the public comment period are encouraged to pre-register by submitting a request in writing prior to close of business on Monday, May 16, 2016, to Stefanie K. Davis, Assistant General Counsel, at *sdavis@lsc.gov.* Those who pre-register will be scheduled to speak first. LSC will transcribe the meeting and make the transcript available to members of the public who are unable to attend. Transcripts and other rulemaking materials will be available at *http://www.lsc.gov/rulemaking-cost-standards-and-property-management-acquisition-and-disposal.* Individuals who wish to listen and/or participate in the proceedings remotely may do so by following the telephone call-in directions provided below.

CALL-IN DIRECTIONS FOR PUBLIC OBSERVATION AND PARTICIPATION:

- Call toll-free number: 1–408–650–3132;
- When prompted, enter the following numeric pass code: 997–871–653.
- When connected to the call, please immediately "MUTE" your telephone.

Members of the public are asked to keep their telephones muted to eliminate background noises. To avoid disrupting the meeting, please refrain from placing the call on hold if doing so will trigger recorded music or other sound. The Workshop moderator will solicit public comment as provided in the following Workshop Agenda.

STATUS OF MEETING: Open.

MATTERS TO BE CONSIDERED:

1. Introductory remarks.

- Charles N.W. Keckler, Chair, Operations and Regulations Committee

2. Panelist introductions.

- AnnaMarie Johnson, Nevada Legal Services
- Frank Bittner and Jose Padilla, California Rural Legal Assistance
- Shamim Huq, Legal Aid Society of Northeastern New York
- Patrick McClintock, Iowa Legal Aid Foundation
- Steve Pelletier, Northwest Justice Project
- Diana White, Legal Assistance Foundation of Metropolitan Chicago
- George Elliott, Legal Aid of Northwest Texas
- Jon Asher, Colorado Legal Services
- Steve Ogilvie, Inland Counties Legal Services
- Robin Murphy, National Legal Aid and Defender Association

3. Discussion of LSC's proposal regarding prior approval for acquisition of property.
4. Discussion of LSC's proposal to include services contracts within the scope of part 1630 and the PAMM.
5. Discussion of LSC's proposal to license intellectual property developed with LSC funds.
6. Discussion of LSC's proposal regarding disposal of property acquired with LSC funds.
7. Public comment.
8. Closing remarks.

- Charles N.W. Keckler, Chair, Operations and Regulations Committee

CONTACT PERSON FOR INFORMATION: Stefanie K. Davis, Assistant General Counsel, at (202) 295–1563. Questions may be sent by electronic mail to *sdavis@lsc.gov.*

ACCESSIBILITY: LSC complies with the Americans with Disabilities Act and Section 504 of the 1973 Rehabilitation Act. Upon request, meeting notices and materials will be made available in alternative formats to accommodate individuals with disabilities. Individuals who need other accommodations due to disability in order to attend the meeting in person or telephonically should contact Stefanie Davis, at (202) 295–1563 or *sdavis@lsc.gov,* at least 2 business days in advance of the meeting. If a request is made without advance notice, LSC will make every effort to accommodate the request but cannot guarantee that all requests can be fulfilled.

Dated: May 6, 2016.

Stefanie K. Davis,

Assistant General Counsel.

[FR Doc. 2016–11066 Filed 5–6–16; 4:15 pm]

BILLING CODE 7050–01–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: (16–034)]

Applied Sciences Advisory Committee; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, the National Aeronautics and Space Administration (NASA) announces a meeting of the

Applied Sciences Advisory Committee (ASAC). This Committee functions in an advisory capacity to the Director, Earth Science Division, in the NASA Science Mission Directorate. The meeting will be held for the purpose of soliciting, from the applied sciences community and other persons, scientific and technical information relevant to program planning.

DATES: Tuesday, May 31, 2016, 12:00 p.m. to 3:00 p.m., Eastern Daylight Time (EDT).

FOR FURTHER INFORMATION CONTACT: Ms. Ann Delo, Science Mission Directorate, NASA Headquarters, Washington, DC 20546, (202) 358–0750, fax (202) 358–2779, or *ann.b.delo@nasa.gov.*

SUPPLEMENTARY INFORMATION: This meeting will be open to the public telephonically and by WebEx. You must use a touch-tone phone to participate in this meeting. Any interested person may dial the USA toll free conference call number (888) 469–2034, passcode 1671423, followed by the # sign, to participate in this meeting by telephone. The WebEx link is *https://nasa.webex.com/;* the meeting number is 997 185 050 and the password is @May31st.

The agenda for the meeting includes the following topics:

- Overview of 2016 Applied Sciences Program Budget
- Continuity Study
- Status of User Working Groups and Science Teams
- Update on Status of Decadal Survey

It is imperative that the meeting be held on this date to accommodate the scheduling priorities of the key participants.

Patricia D. Rausch,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 2016–10842 Filed 5–9–16; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (16–035)]

Notice of Intent To Grant an Exclusive License

AGENCY: National Aeronautics and Space Administration

ACTION: Notice of intent to grant exclusive license.

SUMMARY: This notice is issued in accordance with 35 U.S.C. 209(e) and 37 CFR 404.7(a)(1)(i). The National Aeronautics and Space Administration (NASA) hereby gives notice of its intent to grant an exclusive license in the United State to practice the inventions described and claimed in U.S. Patent Application Number 14/658,584, titled "Infrasonic Stethoscope for Monitoring Physiological Processes," NASA Case Number LAR–18509–1, to Infrasonix, Inc., having its principal place of business in Lawrenceville, GA. Certain patent rights in this invention have been assigned to the United States of America, as represented by the Administrator of the National Aeronautics and Space Administration. The prospective exclusive license will comply with the terms and conditions of 35 U.S.C. 209 and 27 CFR 404.7.

DATES: The prospective exclusive license may be granted unless, within fifteen (15) days from the date of this published notice, NASA receives written objections including evidence and argument that establish that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR. 404.7. Competing applications completed and received by NASA within fifteen (15) days of the date of this published notice will also be treated as objections to the grant of the contemplated exclusive license.

Objections submitted in response to this notice will not be made available to the public for inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

ADDRESSES: Objections relating to the prospective license may be submitted to Patent Counsel, Office of Chief Counsel, MS 30, NASA Langley Research Center, Hampton, Virginia 23681, (757) 864–3221 (phone), (757) 864–9190 (fax).

FOR FURTHER INFORMATION CONTACT: Andrea Z. Warmbier, Patent Attorney, Office of Chief Counsel, MS 30, NASA Langley Research Center, Hampton, Virginia 23681, (757) 864–3221 (phone); (757) 864–9190 (fax); *Andrea.Z.Warmbier@nasa.gov.* Information about other NASA inventions available for licensing can be found online at *http://technology.nasa.gov.*

Mark P. Dvorscak,

Agency Counsel for Intellectual Property.

[FR Doc. 2016–10929 Filed 5–9–16; 8:45 am]

BILLING CODE 7510–13–P

NUCLEAR REGULATORY COMMISSION

[NRC–2016–0093]

Applications and Amendments to Facility Operating Licenses and Combined Licenses Involving No Significant Hazards Considerations

AGENCY: Nuclear Regulatory Commission.

ACTION: Biweekly notice.

SUMMARY: Pursuant to Section 189a. (2) of the Atomic Energy Act of 1954, as amended (the Act), the U.S. Nuclear Regulatory Commission (NRC) is publishing this regular biweekly notice. The Act requires the Commission to publish notice of any amendments issued, or proposed to be issued, and grants the Commission the authority to issue and make immediately effective any amendment to an operating license or combined license, as applicable, upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This biweekly notice includes all notices of amendments issued, or proposed to be issued from April 12 to April 25, 2016. The last biweekly notice was published on April 26, 2016 (81 FR 24659).

DATES: Comments must be filed by June 9, 2016. A request for a hearing must be filed by July 11, 2016.

ADDRESSES: You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2016–0093. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Cindy Bladey, Office of Administration, Mail Stop: OWFN–12–H08, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see "Obtaining Information and Submitting Comments" in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Shirley Rohrer, Office of Nuclear

Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington DC 20555–0001; telephone: 301–415–5411, email: *Shirley.Rohrer@nrc.gov.*

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2016–0093 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2016–0093.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select "*ADAMS Public Documents*" and then select "*Begin Web-based ADAMS Search.*" For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in the **SUPPLEMENTARY INFORMATION** section.
- NRC's PDR: You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2016–0093, facility name, unit number(s), application date, and subject in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *http://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Notice of Consideration of Issuance of Amendments to Facility Operating Licenses and Combined Licenses and Proposed No Significant Hazards Consideration Determination

The Commission has made a proposed determination that the following amendment requests involve no significant hazards consideration. Under the Commission's regulations in § 50.92 of title 10 of the *Code of Federal Regulations* (10 CFR), this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated, (2) create the possibility of a new or different kind of accident from any accident previously evaluated, or (3) involve a significant reduction in a margin of safety. The basis for this proposed determination for each amendment request is shown below.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendment before expiration of the 60-day period provided that its final determination is that the amendment involves no significant hazards consideration. In addition, the Commission may issue the amendment prior to the expiration of the 30-day comment period should circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example in derating or shutdown of the facility. Should the Commission take action prior to the expiration of either the comment period or the notice period, it will publish in the **Federal Register** a notice of issuance. Should the Commission make a final No Significant Hazards Consideration Determination, any hearing will take place after issuance. The Commission expects that the need to take this action will occur very infrequently.

A. Opportunity to Request a Hearing and Petition for Leave to Intervene

Within 60 days after the date of publication of this notice, any person(s) whose interest may be affected by this action may file a request for a hearing and a petition to intervene with respect to issuance of the amendment to the subject facility operating license or combined license. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's "Agency Rules of Practice and Procedure" in 10 CFR part 2. Interested person(s) should consult a current copy of 10 CFR 2.309, which is available at the NRC's PDR, located at One White Flint North, Room O1–F21, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. The NRC's regulations are accessible electronically from the NRC Library on the NRC's Web site at *http://www.nrc.gov/reading-rm/doc-collections/cfr/.* If a request for a hearing or petition for leave to intervene is filed within 60 days, the Commission or a presiding officer designated by the Commission or by the Chief Administrative Judge of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the Chief Administrative Judge of the Atomic Safety and Licensing Board will issue a notice of a hearing or an appropriate order.

As required by 10 CFR 2.309, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements: (1) The name, address, and telephone number of the requestor or petitioner; (2) the nature of the requestor's/petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the requestor's/petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the requestor's/petitioner's interest. The petition must also set forth the specific contentions which the requestor/petitioner seeks to have litigated at the proceeding.

Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the requestor/petitioner shall provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the requestor/petitioner intends to rely in proving the contention at the hearing. The requestor/petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the requestor/petitioner intends to rely to establish those facts or expert opinion. The petition must include sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the requestor/petitioner to relief. A requestor/petitioner who fails to satisfy these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing with respect to resolution of that person's admitted contentions, including the opportunity to present evidence and to submit a cross-examination plan for cross-examination of witnesses, consistent with NRC regulations, policies and procedures.

Petitions for leave to intervene must be filed no later than 60 days from the date of publication of this notice. Requests for hearing, petitions for leave to intervene, and motions for leave to file new or amended contentions that are filed after the 60-day deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i)–(iii). If a hearing is requested, and the Commission has not made a final determination on the issue of no significant hazards consideration, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of any amendment unless the Commission finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

A State, local governmental body, federally-recognized Indian Tribe, or agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h)(1). The petition should state the nature and extent of the petitioner's interest in the proceeding. The petition should be submitted to the Commission by July 11, 2016. The petition must be filed in accordance with the filing instructions in the "Electronic Submissions (E-Filing)" section of this document, and should meet the requirements for petitions for leave to intervene set forth in this section, except that under § 2.309(h)(2) a State, local governmental body, or Federally-recognized Indian Tribe, or agency thereof does not need to address the standing requirements in 10 CFR 2.309(d) if the facility is located within its boundaries. A State, local governmental body, Federally-recognized Indian Tribe, or agency thereof may also have the opportunity to participate under 10 CFR 2.315(c).

If a hearing is granted, any person who does not wish, or is not qualified, to become a party to the proceeding may, in the discretion of the presiding officer, be permitted to make a limited appearance pursuant to the provisions of 10 CFR 2.315(a). A person making a limited appearance may make an oral or written statement of position on the issues, but may not otherwise participate in the proceeding. A limited appearance may be made at any session of the hearing or at any prehearing conference, subject to the limits and conditions as may be imposed by the presiding officer. Persons desiring to make a limited appearance are requested to inform the Secretary of the Commission by July 11, 2016.

B. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least ten 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *hearing.docket@nrc.gov,* or by telephone at 301–415–1677, to request (1) a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a request or petition for hearing (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals/getting-started.html.* System requirements for accessing the E-Submittal server are detailed in the NRC's "Guidance for Electronic Submission," which is available on the agency's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* Participants may attempt to use other software not listed on the Web site, but should note that the NRC's E-Filing system does not support unlisted software, and the NRC Meta System Help Desk will not be able to offer assistance in using unlisted software.

If a participant is electronically submitting a document to the NRC in accordance with the E-Filing rule, the participant must file the document using the NRC's online, Web-based submission form. In order to serve documents through the Electronic Information Exchange System, users will be required to install a Web browser plug-in from the NRC's Web site. Further information on the Web-based submission form, including the installation of the Web browser plug-in, is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.*

Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit a request for hearing or petition for leave to intervene. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* A filing is considered complete at the time the documents are submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC Meta System Help Desk through the "Contact Us" link located on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html,* by email to *MSHD.Resource@nrc.gov,* or by a toll-free call at 1–866–672–7640. The NRC Meta System Help Desk is available between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland, 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket which is available to the public at *http://ehd1.nrc.gov/ehd/,* unless excluded pursuant to an order of the Commission, or the presiding officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. However, in some instances, a request to intervene will require including information on local residence in order to demonstrate a proximity assertion of interest in the proceeding. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

For further details with respect to these license amendment applications, see the application for amendment which is available for public inspection in ADAMS and at the NRC's PDR. For additional direction on accessing information related to this document, see the "Obtaining Information and Submitting Comments" section of this document.

Dominion Nuclear Connecticut, Inc., Docket No. 50–245, Millstone Power Station, Unit No. 1 (MPS1), New London County, Connecticut

Date of amendment request: March 28, 2014. A publicly-available version is in the ADAMS under Accession No. ML14093A028.

Description of amendment request: The amendment would make changes to the MPS1 Permanently Defueled Technical Specifications (PDTSs) by deleting the Table of Contents section and making administrative changes to the PDTSs.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1) Do the proposed changes involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed changes are administrative in nature. The proposed changes remove the PDTS Table of Contents section and make two other administrative changes to the PDTSs. Furthermore, MPS1 has permanently ceased operation and is being maintained in a defueled condition. Therefore, the only credible design basis accident is a fuel handling accident. The administrative changes proposed herein are not initiators of any fuel handling accident previously evaluated, and, consequently, the probability and consequences of a fuel handling accident previously evaluated is not significantly increased.

Therefore, the proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

2) Do the proposed changes create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed changes are administrative in nature, therefore no new or different accidents result from the proposed changes. The changes do not involve a physical alteration of the plant (*i.e.,* no new or different type of equipment will be installed), a change in the method of plant operation, or new operator actions. The changes do not alter assumptions made in the safety analysis.

Therefore, the proposed changes do not create the possibility of a new or different kind of accident from any previously evaluated.

3) Do the proposed changes involve a significant reduction in the margin of safety?

Response: No.

The proposed administrative changes do not involve a change in the method of plant operation, do not affect any accident analyses, and do not relax any safety system settings.

Therefore, the proposed changes do not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Lillian M. Cuoco, Senior Counsel, Dominion Resource Services, Inc., 120 Tredegar Street, RS–2, Richmond, VA 23219.

NRC Branch Chief: Bruce A. Watson.

Duke Energy Carolinas, LLC, Docket Nos. 50–369 and 50–370, McGuire Nuclear Station, Units 1 and 2, Mecklenburg County, North Carolina

Date of amendment request: February 18, 2016. A publicly-available version is in ADAMS under Accession No. ML16076A413.

Description of amendment request: The amendment would allow a one-time extension to the 10-year frequency of the McGuire Nuclear Station, Units 1 and 2, containment leakage rate tests. The change would extend the period from 10 years to 10.5 years for each unit.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed amendment to the Technical Specifications (TS) involves the extension of the McGuire Nuclear Station (MNS) Type A containment integrated leak rate test interval to 10.5 years. The current Type A test interval of 120 months (10 years) would be extended on a one-time basis to no longer than 10.5 years from the last Type A test. This extension is bounded by the 15 month extension, permissible only for non-routine emergent conditions, allowed in accordance with NEI [Nuclear Energy Institute] 94–01 revision 0. The proposed extension also does not change the test method or procedure. The containment is designed to provide an essentially leak tight barrier against the uncontrolled release of radioactivity to the environment for postulated accidents. The containment and the testing requirements invoked to periodically demonstrate the integrity of the containment exist to ensure the plant's ability to mitigate the consequences of an accident, and do not involve the prevention or identification of any precursors of an accident. The change in dose risk for changing the Type A test frequency from 10 years to 10.5 years, measured, as an increase to the total integrated plant risk for those accident sequences influenced by Type A testing, is 0.023 person-rem/year. EPRI [Electric Power Research Institute] Report No. 1009325, Revision 2–A states that a very small population dose is defined as an increase of ≤ 1.0 person-rem per year, or ≤ 1% of the total population dose, whichever is less restrictive for the risk impact assessment of the extended ILRT [integrated leak rate test] intervals. Therefore, this proposed extension does not involve a significant increase in the probability of an accident previously evaluated.

As documented in NUREG–1493, Performance-Based Containment Leak-Test Program, Type B and C tests have identified a very large percentage of containment leakage paths, and the percentage of containment leakage paths that are detected only by Type A testing is very small. The MNS Type A test history supports this conclusion.

The integrity of the containment is subject to two types of failure mechanisms that can be categorized as: (1) Activity based, and; (2) time based as previously discussed. Activity based failure mechanisms are defined as degradation due to system and/or component modifications or maintenance. Local leak rate test requirements and administrative controls such as configuration management and procedural requirements for system restoration ensure that containment integrity is not degraded by plant modifications or maintenance activities. The design and construction requirements of the containment combined with the containment inspections performed in accordance with ASME Section XI, the Maintenance Rule, and TS requirements serve to provide a high degree of assurance that the containment would not degrade in a manner that is detectable only by a Type A test. Based on the above, the proposed extensions do not significantly increase the consequences of an accident previously evaluated.

Therefore, the proposed change does not result in a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed amendment to the TS involves the extension of the MNS Type A containment integrated leak rate test interval from 10 years to 10.5 years. The current Type A test interval of 120 months (10 years) would be extended on a one-time basis to 10.5 years from the last Type A test. The containment and the testing requirements to periodically demonstrate the integrity of the containment exist to ensure the plant's ability to mitigate the consequences of an accident do not involve any accident precursors or initiators. The proposed change does not involve a physical change to the plant (*i.e.,* no new or different type of equipment will be installed) or a change to the manner in which the plant is operated or controlled.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed amendment involve a significant reduction in the margin of safety?

Response: No.

The proposed amendment to TS 5.5.2 involves the extension of the MNS Type A containment integrated leak rate test interval to 10.5 years. The current Type A test interval of 120 months (10 years) would be extended on a one-time basis to no longer than 10.5 years from the last Type A test. This amendment does not alter the manner in which safety limits, limiting safety system set points, or limiting conditions for operation are determined. The specific requirements and conditions of the TS Containment Leak Rate Testing Program exist to ensure that the degree of containment structural integrity and leak tightness that is considered in the plant safety analysis is maintained. The overall containment leak rate limit specified by TS is maintained.

The proposed change involves only the extension of the interval between Type A containment leak rate tests for MNS. The proposed surveillance interval extension is bounded by the 15-year ILRT interval currently authorized within NEI 94–01, Revisions 2–A and 3–A. Industry experience supports the conclusion that Type B and C testing detects a large percentage of containment leakage paths and that the percentage of containment leakage paths that are detected only by Type A testing is small. The containment inspections performed in accordance with ASME Section XI, and TS serve to provide a high degree of assurance that the containment would not degrade in a manner that is detectable only by Type A testing. The combination of these factors ensures that the margin of safety in the plant safety analysis is maintained. The design, operation, testing methods and acceptance criteria for Type A, B, and C containment leakage tests specified in applicable codes and standards would continue to be met, with the approval of this proposed change, since these are not affected by changes to the Type A test intervals.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Lara S. Nichols, Deputy General Counsel, Duke Energy Corporation, 526 South Church Street—EC07H, Charlotte, NC 28202.

NRC Branch Chief: Michael T. Markley.

Exelon Generation Company, LLC, Docket No. 50–461, Clinton Power Station (CPS), Unit No. 1, DeWitt County, Illinois

Date of amendment request: January 25, 2016, as supplemented by letter dated March 31, 2016. A publicly-available version is in ADAMS under Accession Nos. ML16025A182 and ML16076A077.

Description of amendment request: The proposed amendment would revise the technical specifications (TSs) to allow a permanent extension of the Type "A" integrated leak rate testing and Type "C" leak rate testing frequencies. This request also proposes to delete information in TS 5.5.13 regarding a completed requirement to perform Type "C" testing in 2008.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed activity involves the extension of the Clinton Power Station (CPS), Unit 1, Type A containment test interval to

15 years, and the extension of the Type C test interval to 75 months. The current Type A test interval of 120 months (10 years) would be extended on a permanent basis to no longer than 15 years from the last Type A test. The current Type C test interval of 60 months for selected components would be extended on a performance basis to no longer than 75 months. Extensions of up to nine months (total maximum interval of 84 months for Type C tests) are permissible only for non-routine emergent conditions. The proposed extension does not involve either a physical change to the plant or a change in the manner in which the plant is operated or controlled. The containment is designed to provide an essentially leak tight barrier against the uncontrolled release of radioactivity to the environment for postulated accidents. As such, the containment and the testing requirements invoked to periodically demonstrate the integrity of the containment exist to ensure the plant's ability to mitigate the consequences of an accident, and do not involve the prevention or identification of any precursors of an accident.

The change in dose risk for changing the Type A Integrated Leak Rate Test (ILRT) interval from three-per-ten years to once-per-fifteen-years, measured as an increase to the total integrated dose risk for all accident sequences, is 3.80E–03 person-rem/yr using the EPRI [Electric Power Research Institute] guidance with the base case corrosion included. This change meets both of the related acceptance criteria for change in population dose of less than 1.0 person-rem/yr or less than 1% person-rem/yr. The change in dose risk drops to 9.37E–04 person-rem/yr when using the EPRI Expert Elicitation methodology. The change in dose risk meets both of the related acceptance for change in population dose of less than 1.0 person-rem/yr or less than 1% person-rem/yr. Therefore, this proposed extension does not involve a significant increase in the probability of an accident previously evaluated.

In addition, as documented in NUREG–1493, Types B and C tests have identified a very large percentage of containment leakage paths, and the percentage of containment leakage paths that are detected only by Type A testing is very small. The CPS, Unit 1 Type A test history supports this conclusion.

The integrity of the containment is subject to two types of failure mechanisms that can be categorized as: (1) Activity based, and, (2) time based. Activity based failure mechanisms are defined as degradation due to system and/or component modifications or maintenance. Local leak rate test requirements and administrative controls such as configuration management and procedural requirements for system restoration ensure that containment integrity is not degraded by plant modifications or maintenance activities. The design and construction requirements of the containment combined with the containment inspections performed in accordance with American Society of Mechanical Engineers (ASME) Section XI, and Technical Specifications (TS) requirements serve to provide a high degree of assurance that the containment would not degrade in a manner that is detectable only by a Type A test. Based on the above, the proposed extensions do not significantly increase the consequences of an accident previously evaluated.

The proposed amendment also deletes an exception previously granted to allow one-time extension of the ILRT test frequency for CPS. This exception was for an activity that has already taken place; therefore, this deletion is solely an administrative action that does not result in any change in how CPS is operated.

Therefore, the proposed change does not result in a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed amendment to the TS 5.5.13, "Primary Containment Leakage Rate Testing Program," involves the extension of the CPS, Unit 1 Type A containment test interval to 15 years and the extension of the Type C test interval to 75 months. The containment and the testing requirements to periodically demonstrate the integrity of the containment exist to ensure the plant's ability to mitigate the consequences of an accident.

The proposed change does not involve a physical change to the plant (*i.e.,* no new or different type of equipment will be installed) nor does it alter the design, configuration, or change the manner in which the plant is operated or controlled beyond the standard functional capabilities of the equipment.

The proposed amendment also deletes an exception previously granted to allow one-time extension of the ILRT test frequency for CPS. This exception was for an activity that has already taken place; therefore, this deletion is solely an administrative action that does not result in any change in how CPS is operated.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The proposed amendment to TS 5.5.13 involves the extension of the CPS, Unit 1 Type A containment test interval to 15 years and the extension of the Type C test interval to 75 months for selected components. This amendment does not alter the manner in which safety limits, limiting safety system set points, or limiting conditions for operation are determined. The specific requirements and conditions of the TS Containment Leak Rate Testing Program exist to ensure that the degree of containment structural integrity and leaktightness that is considered in the plant safety analysis is maintained. The overall containment leak rate limit specified by TS is maintained.

The proposed change involves the extension of the interval between Type A containment leak rate tests and Type C tests for CPS, Unit 1. The proposed surveillance interval extension is bounded by the 15-year ILRT interval and the 75-month Type C test interval currently authorized within NEI [Nuclear Energy Institute] 94–01, Revision 3–A. Industry experience supports the conclusion that Type B and C testing detects a large percentage of containment leakage paths and that the percentage of containment leakage paths that are detected only by Type A testing is small. The containment inspections performed in accordance with ASME Section XI, and TS serve to provide a high degree of assurance that the containment would not degrade in a manner that is detectable only by Type A testing. The combination of these factors ensures that the margin of safety in the plant safety analysis is maintained. The design, operation, testing methods and acceptance criteria for Type A, B, and C containment leakage tests specified in applicable codes and standards would continue to be met, with the acceptance of this proposed change, since these are not affected by changes to the Type A and Type C test intervals.

The proposed amendment also deletes exceptions previously granted to allow one time extensions of the ILRT test frequency for CPS, Unit 1. This exception was for an activity that has taken place; therefore, the deletion is solely an administrative action and does not change how CPS is operated and maintained. Thus, there is no reduction in any margin of safety.

Therefore, the proposed changes do not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Bradley J. Fewell, Associate General Counsel, Exelon Nuclear, 4300 Winfield Road, Warrenville, IL 60555.

NRC Acting Branch Chief: Justin C. Poole.

Exelon Generation Company, LLC, Docket No. 50–410, Nine Mile Point Nuclear Station, Unit 2, Oswego County, New York

Date of amendment request: February 23, 2016. A publicly-available version is in ADAMS under Accession No. ML16054A359.

Description of amendment request: The amendment would revise the Technical Specifications to incorporate previously NRC-approved Industry/Technical Specification Task Force 439 (TSTF–439), Revision 2, "Eliminate Second Completion Times Limiting Time From Discovery of Failure To Meet an LCO."

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change eliminates certain Completion Times from the Technical Specifications. Completion Times are not an initiator to any accident previously evaluated. As a result, the probability of an accident previously evaluated is not affected. The consequences of an accident during the revised Completion Time are no different than the consequences of the same accident during the existing Completion Times. As a result, the consequences of an accident previously evaluated are not affected by this change. The proposed change does not alter or prevent the ability of SSCs [systems, structures, and components] from performing their intended function to mitigate the consequences of an initiating event within the assumed acceptance limits. The proposed change does not affect the source term, containment isolation, or radiological release assumptions used in evaluating the radiological consequences of an accident previously evaluated. Further, the proposed change does not increase the types or amounts of radioactive effluent that may be released offsite, nor significantly increase individual or cumulative occupational/public radiation exposures. The proposed change is consistent with the safety analysis assumptions and resultant consequences. Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed change does not involve a physical alteration of the plant (*i.e.*, no new or different type of equipment will be installed) or a change in the methods governing normal plant operation. The proposed change does not alter any assumptions made in the safety analysis. Therefore, the proposed change does not create the possibility of anew or different kind of accident from any accident previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

The proposed change to delete the second Completion Time does not alter the manner in which safety limits, limiting safety system settings or limiting conditions for operation are determined. The safety analysis acceptance criteria are not affected by this change. The proposed change will not result in plant operation in a configuration outside of the design basis. Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Tamra Domeyer, Associate General Counsel, Exelon Generation Company, LLC, 4300 Winfield Road, Warrenville, IL 60555.

NRC Branch Chief: Travis L. Tate.

Exelon Generation Company, LLC, Docket Nos. 50–220 and 50–410, Nine Mile Point Nuclear Station (NMPNS), Units 1 and 2, Oswego County, New York

Date of amendment request: March 18, 2016. A publicly-available version is in ADAMS under Accession No. ML16078A065.

Description of amendment request: The amendment would revise the Technical Specifications (TS) concerning a change to the method of calculating core reactivity for the purpose of performing the Reactivity Anomalies surveillance at NMPNS, Units 1 and 2.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed TS changes do not affect any plant systems, structures, or components designed for the prevention or mitigation of previously evaluated accidents. The amendment would only change how the Reactivity Anomalies surveillance is performed. Verifying that the core reactivity is consistent with predicted values ensures that accident and transient safety analyses remain valid. This amendment changes the TS requirements such that, rather than performing the surveillance by comparing predicted to actual control rod density, the surveillance is performed by a direct comparison of k_{eff}.

Therefore, since the Reactivity Anomalies surveillance will continue to be performed by a viable method, the proposed amendment does not involve a significant increase in the probability or consequence of a previously evaluated accident.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

This TS amendment request does not involve any changes to the operation, testing, or maintenance of any safety-related, or otherwise important to safety systems. All systems important to safety will continue to be operated and maintained within their design bases. The proposed changes to the Reactivity Anomalies surveillance will only provide a new, more efficient method of detecting an unexpected change in core reactivity.

Since all systems continue to be operated within their design bases, no new failure modes are introduced and the possibility of a new or different kind of accident is not created.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

This proposed TS amendment proposes to change the method for performing the Reactivity Anomalies surveillance from a comparison of predicted to actual control rod density to a comparison of predicted to monitored k_{eff}. The direct comparison of k_{eff} provides a technically superior method of calculating any differences in the expected core reactivity. The Reactivity Anomalies surveillance will continue to be performed at the same frequency as is currently required by the TS, only the method of performing the surveillance will be changed. Consequently, core reactivity assumptions made in safety analyses will continue to be adequately verified.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Tamra Domeyer, Associate General Counsel, Exelon Generation Company, LLC, 4300 Winfield Road, Warrenville, IL 60555.

NRC Branch Chief: Travis L. Tate.

Exelon Generation Company, LLC, Docket Nos. STN 50–456 and STN 50–457, Braidwood Station, Units 1 and 2, Will County, Illinois and Docket Nos. STN 50–454 and STN 50–455, Byron Station, Unit Nos. 1 and 2, Ogle County, Illinois

Date of amendment request: February 23, 2016. A publicly-available version is in ADAMS under Accession No. ML16055A149.

Description of amendment request: The amendment would (1) revise Technical Specification (TS) 4.2.1, "Reactor Core, Fuel Assemblies," to add Optimized ZIRLO™, as an approved fuel rod cladding material, (2) revise TS 5.6.5.b to add the Westinghouse topical reports for Optimized ZIRLO™ and ZIRLO®, and (3) revise TS 5.6.5.b with a non-technical change to the Reference 11 title (replace a semicolon with a period).

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

EGC [Exelon Generation Company] has evaluated the proposed changes for Braidwood and Byron, using the criteria in 10 CFR 50.92, and has determined that the proposed changes do not involve a significant hazards consideration. The following information is provided to support a finding of no significant hazards consideration.

Criteria

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change would allow the use of Optimized ZIRLO™ clad nuclear fuel in the reactors. The NRC approved topical report WCAP–12610–P–A & CENPD–404–P–A, Addendum 1–A, "Optimized ZIRLO™ prepared by Westinghouse Electric Company LLC (Westinghouse), addresses Optimized ZIRLO™ and demonstrates that Optimized ZIRLO™ has essentially the same properties as currently licensed ZIRLO®. The fuel cladding itself is not an accident initiator and does not affect accident probability. With the approved exemption, use of Optimized ZIRLO™ fuel cladding will continue to meet all 10 CFR 50.46 acceptance criteria and, therefore, will not increase the consequences of an accident. Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

Use of Optimized ZIRLO™ clad fuel will not result in changes in the operation or configuration of the facility. Topical Report WCAP–12610–P–A & CENPD–404–P–A, Addendum 1–A, demonstrated that the material properties of Optimized ZIRLO™ are similar to those of standard ZIRLO®. Therefore, Optimized ZIRLO™ fuel rod cladding will perform similarly to those fabricated from standard ZIRLO® thus precluding the possibility of the fuel cladding becoming an accident initiator and causing a new or different type of accident.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The proposed change will not involve a significant reduction in the margin of safety. Topical Report WCAP–12610–P–A & CENPD–404–P–A, Addendum 1–A, demonstrated that the material properties of the Optimized ZIRLO™ are not significantly different from those of standard ZIRLO®. Optimized ZIRLO™ is expected to perform similarly to standard ZIRLO® for all normal operating and accident scenarios, including both loss of coolant accident (LOCA) and non-LOCA scenarios. For LOCA scenarios, where the slight difference is Optimized ZIRLO™ material properties relative to standard ZIRLO® could have some impact on the overall accident scenario, plant-specific LOCA analyses using Optimized ZIRLO™ properties will demonstrate that the acceptance criteria of 10 CFR 50.46 have been satisfied. Therefore, the proposed change does not involve a significant reduction in a margin of safety.

Based on the above, EGC concludes that the proposed amendment to allow the use of Optimized ZIRLO™ fuel cladding material does not involve a significant hazards consideration under the standards set forth in 10 CFR 50.92(c), and, accordingly, a finding of "no significant hazards consideration" is justified.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Bradley J. Fewell, Associate General Counsel, Exelon Nuclear, 4300 Winfield Road, Warrenville, IL 60555.

NRC Acting Branch Chief: Justin C. Poole.

FirstEnergy Nuclear Operating Company, Docket No. 50–440, Perry Nuclear Power Plant, Unit No. 1, Lake County, Ohio

Date of amendment request: March 15, 2016. A publicly-available version is in ADAMS under Accession No. ML16075A411.

Description of amendment request: The proposed amendment would revise Technical Specification (TS) 3.6.2.2, "Suppression Pool Water Level," as well as TS surveillance requirements 3.6.2.4.1 and 3.6.2.4.4 associated with TS 3.6.2.4, "Suppression Pool Makeup System (SPMU)," to allow installation of the reactor well to steam dryer storage pool gate in the upper containment pool (UCP) in MODES 1, 2, and 3. The proposed amendment would also create new special operations TS 3.10.9, "Suppression Pool Makeup—MODE 3 Upper Containment Pool Drain-Down," to allow draining of the reactor well portion of the UCP in MODE 3.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The changes proposed in the license amendment request specify different water level requirements in the upper containment pool and suppression pool to permit gate installation in MODES 1, 2, and 3, and drain-down of the reactor well in MODE 3. The probability of an accident previously evaluated is unrelated to the water level in these pools, since they are mitigating systems. The operation or failure of a mitigating system does not contribute to the occurrence of an accident. No active or passive failure mechanisms that could lead to an accident are affected by these proposed changes.

Suppression pool water levels are increased during upper pool gate installation in MODES 1, 2, and 3 and during reactor well drain-down in MODE 3, with a potential for an increased probability of drywell flooding during an inadvertent dump of the upper containment pool. An inadvertent dump of the upper pool during any period of operation with a pressurized vessel does not represent, in and of itself, any significant hazard to the public, the plant operating personnel, or any plant equipment. The piping components which would be affected in this event have been analyzed for the flooding effect, and it has been determined that this event could not initiate a loss of coolant accident (LOCA).

The changes have no impact on the ability of any of the emergency core cooling systems (ECCS) to function adequately, since adequate net positive suction head (NPSH) is maintained. The increase in suppression pool water level to compensate for the reduction in UCP volume will provide reasonable assurance that the minimum post-accident vent coverage is adequate to assure the pressure suppression function of the suppression pool is accomplished. The suppression pool water level will be raised above the current high water level for the proposed reactor well drain-down activity only after the reactor pressure has been reduced sufficiently to assure that the hydrodynamic loads from a loss of coolant accident will not exceed the design values. The reduced reactor pressure will also ensure that the loads due to main steam safety relief valve actuation with an elevated pool level are within the design loads.

Relative to dose rates on the refuel floor, the resultant dose rates from the reactor in MODES 3 and 4 are the same regardless of a drain-down of the upper pool reactor well. Relative to a low pressure LOCA in MODE 3, the reduced post-LOCA containment pressure and the decay time to reach MODE 3 conditions ensures that post-accident dose consequences are bounded by the design-basis accident LOCA.

Therefore, the proposed amendment does not significantly increase the probability or consequences of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from an accident previously evaluated?

Response: No.

The proposed changes specify different water level requirements in the upper containment pool and suppression pool to permit gate installation in MODES 1, 2, and 3, and drain-down of the reactor well in MODE 3. These changes do not affect or alter the ability of the suppression pool makeup

(SPMU) system to perform its design function. The proposed change in the pool water levels will maintain the design function of mitigating the pressure and temperature increase generated by a LOCA, and will maintain the required drywell vent coverage during post-accident ECCS draw down.

The altered water levels in the pools do not create a different type of accident than presently evaluated. With the reduced pressure in the reactor coolant system, the GOTHIC computer program simulations demonstrate that the accident responses at defined conditions with the reactor well drained in MODE 3 are bounded by the current design basis accidents.

Therefore, the proposed amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

The proposed changes to the UCP and the suppression pool water levels do not introduce any new setpoints at which protective or mitigating actions are initiated. Current instrument setpoints remain unaltered by this change. Although the water levels are adjusted for the UCP gate installation and the reactor well drain-down activity, the design and functioning of the containment pressure suppression system remains unchanged. The proposed total water volume is sufficient to provide high confidence that the pressure suppression and containment systems will be capable of mitigating large and small break accidents. All analyzed accident results remain within the design values for the structures and equipment.

Therefore, the proposed amendment does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: David W. Jenkins, Attorney, FirstEnergy Corporation, Mail Stop A–GO–15, 76 South Main Street, Akron, OH 44308.

NRC Branch Chief: David J. Wrona.

Pacific Gas and Electric Company (PG&E), Docket Nos. 50–275 and 50–323, Diablo Canyon Nuclear Power Plant, Units 1 and 2, San Luis Obispo County, California

Date of amendment request: March 23, 2016. A publicly-available version is in ADAMS under Accession No. ML16084A588.

Description of amendment request: The proposed amendment would revise Technical Specification (TS) 3.4.12, "Low Temperature Overpressure Protection (LTOP) System," to reflect the mass input transient analysis that assumes an emergency core cooling system (ECCS) centrifugal charging pump (CCP) and the normal charging pump (NCP) capable of simultaneously injecting into the reactor coolant system (RCS) during TS 3.4.12 applicability.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change revises TS 3.4.12 to allow an ECCS CCP and the NCP aligned to LTOP orifice to be capable of injecting into the RCS during low RCS pressures and temperatures. The LCO [Limiting Condition for Operation] provides RCS overpressure protection by having a minimum coolant input capability and have adequate pressure relief capability. Analyses have demonstrated that one power operated relief valve (PORV) or an RCS vent of at least 2.07 square inches is capable of limiting the RCS pressure excursions below the 10 CFR 50, Appendix G limits for the design basis LTOP limits.

The proposed change does not adversely affect accident initiators or precursors, nor alter the design assumptions, conditions, and configuration of the facility or the manner in which the plant is operated and maintained. The proposed change does not adversely affect the ability of structures, systems, and components to perform their intended safety function to mitigate the consequences of an initiating event within the assumed acceptance limits. The proposed change does not affect the source term, containment isolation, or radiological release assumptions used in evaluating the radiological consequences of any accident previously evaluated. Further, the proposed change does not increase the types and amounts of radioactive effluent that may be released offsite, nor significantly increase individual or cumulative occupational/public radiation exposure.

The NRC has previously evaluated a similar LAR [license amendment request] related to Wolf Creek Generating Station. In Amendment No. 207, the NRC concluded that the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated [ADAMS Accession No. ML13282A534].

In 2007, PG&E replaced the Unit 1 non-safety-related PDP [positive displacement pump] with a non-safety-related CCP, called the NCP, in order to alleviate operational issues associated with the PDP. In 2008, PG&E performed the replacement on Unit 2. PG&E also designed, tested, and installed an FCO [flow choking orifice] called the LTOP orifice to be used during LTOP operation to ensure that the total maximum mass injection capability with the NCP remained bounded by the LTOP mass injection analysis. These changes were implemented under 10 CFR 50.59. However, no physical changes are being made to the plant as a result of the proposed license amendment.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different accident from any accident previously evaluated?

Response: No.

The proposed change revises TS 3.4.12 to allow an ECCS CCP and the NCP aligned to LTOP orifice to be capable of simultaneously injecting into the RCS during low RCS pressures and temperatures. The LCO provides RCS overpressure protection by having a minimum coolant input capability and have adequate pressure relief capability. Analyses have demonstrated that one PORV or an RCS vent of at least 2.07 square inches is capable of limiting the RCS pressure excursions below the 10 CFR 50, Appendix G limits for the design basis LTOP limits.

The proposed change will not physically alter the plant (no new or different type of equipment will be installed) or change the methods governing normal plant operation. The proposed change does not introduce new accident initiators or impact assumptions made in the safety analysis. Testing requirements continue to demonstrate that the LCOs are met and the system components are functional.

Therefore, the proposed change does not create the possibility of a new or different accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The proposed change does not alter the manner in which safety limits, limiting safety system settings, or limiting conditions for operation are determined. The safety analysis acceptance criteria are not impacted by this change. The proposed change will not result in plant operation in a configuration outside the design basis.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment requests involve no significant hazards consideration.

Attorney for licensee: Jennifer Post, Esq., Pacific Gas and Electric Company, P.O. Box 7442, San Francisco, CA 94120.

NRC Branch Chief: Robert J. Pascarelli.

South Carolina Electric and Gas Company, Docket Nos. 52–027 and 52–028, Virgil C. Summer Nuclear Station (VCSNS) Units 2 and 3, Fairfield County, South Carolina

Date of amendment request: March 4, 2016. A publicly-available version is in ADAMS under Accession No. ML16067A145.

Description of amendment request: The proposed changes, if approved, would amend Combined License (COL) No. NPF–93 and NPR–94 for the VCSNS. The requested amendment proposed changes would depart from the approved AP1000 Design Control Document (DCD) "Tier 2" and "Tier 2*" information as currently incorporated into the VCSNS Updated Final Safety Analysis Report (UFSAR). The changes relate to updating the UFSAR text and tables; and information incorporated by reference related to Westinghouse Electric Company's Reports WCAP–16096, "Software Program Manual for Common Q™ Systems," (also known as the Common Q SPM) Revision 4, WCAP–16097, "Common Qualified Platform Topical Report," (also known as the Common Q Topical Report) Revision 3, and WCAP–15927, "Design Process for AP1000 Common Q Safety Systems," Revision 4; and associated documents and references such as a reference to the NRC's Regulatory Guide 1.152, "Criteria for Use of Computers in Safety Systems of Nuclear Power Plants" (Revision 3, July 2011), and its associated exceptions. The proposed changes also include removal of Tier 2* WCAP–17201–P, "AC160 High Speed Link Communication Compliance to DI&C–ISG–04 Staff Positions 9, 12, 13 and 15 Technical Report," as a UFSAR incorporated by reference document.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

WCAP–16096 (Common Q Software Program Manual) was updated to Revision 4 to reference later NRC endorsed regulatory guides and standards and update the requirements for the software design and development processes for the Common Q portion of the AP1000 Protection and Safety Monitoring System (PMS). WCAP–16097 (Common Q Topical Report) was updated to Revision 3 to describe new Common Q components and standards currently used for the AP1000 PMS implementation of the Common Q platform. These two WCAPs have been reviewed and approved by the NRC in Safety Evaluations dated February 7, 2013. WCAP–15927 was updated to reference the newest revisions of WCAP–16096 and WCAP–16097 and for editorial corrections. The proposed activity adopts the updated versions as incorporated by reference documents into the Updated Final Safety Analysis Report. Other proposed document changes support the implementation of the updated versions of WCAP–16096, WCAP–16097, and WCAP–15927.

The Common Q platform is an acceptable platform for nuclear safety-related applications. The Common Q system meets the requirements of 10 CFR part 50, Appendix A, General Design Criteria (Criteria 1, 2, 4, 13, 19, 20, 21, 22, 23, 24, and 25), the Institute of Electrical and Electronics Engineers (IEEE) Standard 603–1991 for the design of safety-related reactor protection systems, engineered safety features systems and other plant systems, and the guidelines of Regulatory Guide 1.152 and supporting industry standards for the design of digital systems.

Because the Common Q platform and the Protection and Safety Monitoring System (PMS) implementation of the Common Q platform meet the criteria in the applicable General Design Criteria, the revisions to these documents do not affect the prevention and mitigation of abnormal events, such as accidents, anticipated operational occurrences, earthquakes, floods and turbine missiles, or their safety or design analyses as described in the licensing basis. The incorporation of the updated documents does not adversely affect the interface with any structure, system, or component (SSC) accident initiator or initiating sequence of events. Thus, the probabilities of the accidents previously evaluated in the UFSAR are not affected.

Therefore, the proposed activity does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed changes to adopt the updated WCAP–16096, WCAP–16097, and WCAP–15927 into the UFSAR do not adversely affect the design or operation of safety-related equipment or equipment whose failure could initiate an accident beyond what is already described in the licensing basis. These changes do not adversely affect fission product barriers. No safety analysis or design basis acceptance limit/criterion is challenged or exceeded by the requested change.

Therefore, this activity does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

The proposed changes to adopt the updated WCAP–16096, WCAP–16097, and WCAP–15927 into the UFSAR do not adversely affect the design, construction, or operation of any plant SSCs, including any equipment whose failure could initiate an accident or a failure of a fission product barrier. No analysis is adversely affected by the proposed changes. Furthermore, no system function, design function, or equipment qualification will be adversely affected by the changes.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Kathryn M. Sutton, Morgan, Lewis & Bockius LLC, 1111 Pennsylvania Avenue NW, Washington, DC 20004–2514.

NRC Acting Branch Chief: John McKirgan.

South Carolina Electric and Gas Company, Docket Nos. 52–027 and 52–028, Virgil C. Summer Nuclear Station (VCSNS), Units 2 and 3, Fairfield County, South Carolina

Date of amendment request: March 14, 2016. A publicly-available version is in ADAMS under Accession No. ML16075A264.

Description of amendment request: The proposed change would amend the Combined License (COL) No. NPF–93 and NPF–94 for the VCSNS. The requested amendment proposes to depart from approved AP1000 Design Control Document (DCD) Tier 2 information (text, tables, and figures) and involved Tier 2* information (as incorporated into the Updated Final Safety Analysis Report as plant specific DCD information), and also involves a change to the plant-specific Technical Specifications. Specifically, the amendment request proposes changes to the plant-specific AP1000 fuel system design, nuclear design, thermal hydraulic design, and accident analyses as described in the licensing basis documents. These proposed changes are consistent with those generically approved in WCAP–17524–P–A, Revision 1, "AP1000 Core Reference Report."

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed changes will revise the licensing basis documents related to the fuel system design, nuclear design, thermal hydraulic design, and accident analyses.

The UFSAR [Updated Final Safety Analysis Report] Chapter 15 accident analyses describe the analyses of various design basis transients and accidents to demonstrate compliance of the AP1000 design with the acceptance criteria for these events. The acceptance criteria for the various events are based on meeting the relevant regulations, general design criteria, the Standard Review Plan, and are a function of the anticipated frequency of occurrence of the event and potential radiological consequences to the public. As such, each design-basis event is categorized accordingly based on these considerations. As discussed in Section 5.3 of WCAP–17524–P–A Revision 1, the revised accident analyses maintain their plant conditions, and thus their frequency designation and consequence level as previously evaluated. As confirmed in the Safety Evaluation Report (SER), the revised analyses meet the applicable guidelines in the Standard Review Plan.

Therefore, the proposed amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed changes will revise the licensing basis documents related to the fuel system design, nuclear design, thermal hydraulic design, and accident analyses.

The proposed changes would not introduce a new failure mode, fault, or sequence of events that could result in a radioactive material release. The proposed changes do not alter the design, configuration, or method of operation of the plant beyond standard functional capabilities of the equipment.

Therefore, the proposed amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

The proposed changes will revise the licensing basis documents related to the fuel system design, nuclear design, thermal hydraulic design, and accident analyses.

Safety margins are applied at many levels to the design and licensing basis functions and to the controlling values of parameters to account for various uncertainties and to avoid exceeding regulatory or licensing limits. UFSAR Subsection 4.1.1 presents the Principle Design Requirements imposed on the fuel and control rod mechanism design to ensure that the performance and safety criteria described in UFSAR Chapter 4 and Chapter 15 are met. The revised fuel system design, nuclear design, thermal hydraulic design, and accident analyses maintain the same Principle Design Requirements, and further, satisfy the applicable regulations, general design criteria, and Standard Review Plan. The effects of the changes do not result in a significant reduction in margin for any safety function, and were evaluated in the Safety Evaluation Report for WCAP–17524–P–A Revision 1 and found to be acceptable.

Therefore, the proposed amendment does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Kathryn M. Sutton, Morgan, Lewis & Bockius LLC, 1111 Pennsylvania Avenue NW, Washington, DC 20004–2514.

NRC Acting Branch Chief: John McKirgan.

Tennessee Valley Authority, Docket No. 50–390, Watts Bar Nuclear Plant (WBN), Unit 1, Rhea County, Tennessee

Date of amendment request: February 23, 2016. A publicly-available version is in ADAMS under Accession No. ML16054A585.

Description of amendment request: The amendment would revise the WBN Dual Unit Fire Protection Report and would revise the associated License Condition regarding the WBN fire protection program. Specifically, the amendment requests approval of a deviation from the physical separation requirements of 10 CFR part 50, appendix R, section III.G.2.d.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

A fire hazards analysis was performed for the areas under the scope of this amendment. This fire hazards analysis demonstrates that one train of safe shutdown equipment will remain functional in the event of an Appendix R fire, even though a radiant energy shield will not be provided for two raceway containing safe shutdown circuits.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

A fire hazards analysis was performed for the areas under the scope of this amendment. This fire hazards analysis demonstrates that one train of safe shutdown equipment will remain functional in the event of an Appendix R fire, even though a radiant energy shield will not be provided for two raceway containing safe shutdown circuits. Based on this, the proposed amendment will not alter the requirements or function for systems required during accident conditions.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

A fire hazards analysis was performed for the areas under the scope of this amendment. This fire hazards analysis demonstrates that one train of safe shutdown equipment will remain functional in the event of an Appendix R fire, even though a radiant energy shield will not be provided for two raceway containing safe shutdown circuits.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Sherry A. Quirk, Executive Vice President and General Counsel, Tennessee Valley Authority, 400 West Summit Hill Drive, Knoxville, TN 37902.

NRC Branch Chief: Benjamin G. Beasley.

III. Previously Published Notices of Consideration of Issuance of Amendments to Facility Operating Licenses and Combined Licenses, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The following notices were previously published as separate individual notices. The notice content was the same as above. They were published as individual notices either because time did not allow the Commission to wait for this biweekly notice or because the action involved exigent circumstances. They are repeated here because the biweekly notice lists all amendments issued or proposed to be issued involving no significant hazards consideration.

For details, see the individual notice in the **Federal Register** on the day and page cited. This notice does not extend the notice period of the original notice.

Tennessee Valley Authority, Docket No. 50–390 Watts Bar Nuclear Plant, Unit 1, Rhea County, Tennessee

Date of amendment request: March 4, 2016. A publicly-available version is in ADAMS under Accession No. ML16064A488.

Brief description of amendment request: The amendment would revise the Cyber Security Plan implementation schedule for Milestone 8 and would revise the associated license condition in the Facility Operating License.

Date of publication of individual notice in **Federal Register:** April 19, 2016 (81 FR 23011).

Expiration date of individual notice: May 19, 2016 (public comments); June 20, 2016 (hearing requests).

IV. Notice of Issuance of Amendments to Facility Operating Licenses and Combined Licenses

During the period since publication of the last biweekly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR chapter I, which are set forth in the license amendment.

A notice of consideration of issuance of amendment to facility operating license or combined license, as applicable, proposed no significant hazards consideration determination, and opportunity for a hearing in connection with these actions, was published in the **Federal Register** as indicated.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.22(b) and has made a determination based on that assessment, it is so indicated.

For further details with respect to the action see (1) the applications for amendment, (2) the amendment, and (3) the Commission's related letter, Safety Evaluation and/or Environmental Assessment as indicated. All of these items can be accessed as described in the "Obtaining Information and Submitting Comments" section of this document.

DTE Electric Company, Docket No. 50–341, Fermi 2, Monroe County, Michigan

Date of amendment request: September 24, 2015.

Brief description of amendment: The amendment revises Surveillance Requirements (SRs) to verify that the system locations susceptible to gas accumulation are sufficiently filled with water and to provide allowances which permit performance of the verification. The changes address the concerns discussed in NRC Generic Letter (GL) 2008–01, "Managing Gas Accumulation in Emergency Core Cooling, Decay Heat Removal, and Containment Spray Systems," as described in NRC-approved Technical Specifications Task Force (TSTF)-523, Revision 2, "Generic Letter 2008–01, Managing Gas Accumulation."

Date of issuance: April 20, 2016.

Effective date: As of the date of issuance and shall be implemented within 90 days of issuance.

Amendment No.: 204. A publicly-available version is in ADAMS under Accession. No. ML16069A006; documents related to this amendment are listed in the Safety Evaluation enclosed with the amendment.

Facility Operating License No. NPF–43: This amendment revises the Facility Operating License and Technical Specifications.

Date of initial notice in ***Federal Register:*** January 5, 2016 (81 FR 260).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated April 20, 2016.

No significant hazards consideration comments received: No.

Duke Energy Carolinas, LLC, Docket Nos. 50–413 and 50–414, Catawba Nuclear Station, Units 1 and 2, York County, South Carolina

Date of amendment request: April 30, 2015, as supplemented by letter dated February 19, 2016.

Brief description of amendments: The amendments approved adoption of an emergency action level scheme based on Nuclear Energy Institute (NEI) 99–01, Revision 6, "Development of Emergency Action Levels for Non-Passive Reactors," for the Catawba Nuclear Station, Units 1 and 2.

Date of issuance: April 18, 2016.

Effective date: As of the date of issuance and shall be implemented by March 10, 2017.

Amendment Nos.: 279 for Unit 1 and 275 for Unit 2. A publicly-available version is in ADAMS under Accession No. ML16082A038; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

Renewed Facility Operating License Nos. NPF–35 and NPF–52: The amendments revised the Renewed Facility Operating License.

Date of initial notice in ***Federal Register:*** June 23, 2015 (80 FR 35980). The supplemental letter dated February 19, 2016, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated April 18, 2016.

No significant hazards consideration comments received: No.

Duke Energy Carolinas, LLC, Docket Nos. 50–369, 50–370, 50–413, and 50–414, McGuire Nuclear Station, Units 1 and 2, Mecklenburg County, North Carolina and Catawba Nuclear Station, Units 1 and 2, York County, SC

Date of amendment request: June 23, 2015.

Brief description of amendments: The amendments remove superseded TS requirements.

Date of issuance: April 8, 2016.

Effective date: As of the date of issuance and shall be implemented within 30 days of issuance.

Amendment Nos.: 283, 262, 278, and 274. A publicly-available version is in ADAMS under Accession No. ML16060A229; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

Facility Operating License Nos. NPF–9, NPF–17, NPF–35, and NPF–52: Amendments revised the Facility Operating Licenses and Technical Specifications.

Date of initial notice in ***Federal Register:*** August 4, 2015 (80 FR 46347).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated April 8, 2016.

No significant hazards consideration comments received: No.

Duke Energy Progress, Inc., Docket No. 50–400, Shearon Harris Nuclear Power Plant, Unit 1, Wake and Chatham Counties, North Carolina

Date of amendment request: April 30, 2015, as supplemented by letters dated November 19, 2015, and January 28, 2016.

Brief description of amendment: The amendment adopted the NRC-endorsed

Nuclear Energy Institute (NEI) 99–01, Revision 6, "Methodology for the Development of Emergency Action Levels for Non-Passive Reactors."

Date of issuance: April 13, 2016.

Effective date: As of the date of issuance and shall be implemented within 180 days of issuance.

Amendment No.: 149. A publicly-available version is in ADAMS under Accession No. ML16057A838; documents related to this amendment are listed in the Safety Evaluation (SE) enclosed with the amendment.

Facility Operating License No. NPF–63: The amendment revised the Emergency Action Level Technical Bases document.

Date of initial notice in ***Federal Register:*** July 21, 2015 (80 FR 43128). The supplemental letters dated November 19, 2015, and January 28, 2016, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendment is contained in an SE dated April 13, 2016.

No significant hazards consideration comments received: No.

Entergy Nuclear Operations, Inc., Docket Nos. 50–003, 50–247, and 50–286, Indian Point Nuclear Generating Unit Nos. 1, 2, and 3, Westchester County, New York

Date of amendment request: June 16, 2015.

Brief description of amendments: The amendments revised the Cyber Security Plan Milestone 8 full implementation date by extending the full implementation date from June 30, 2016, to December 31, 2017.

Date of issuance: April 12, 2016.

Effective date: As of the date of issuance, and shall be implemented within 30 days of issuance.

Amendment Nos.: 59 (Unit No. 1), 284 (Unit No. 2), and 260 (Unit No. 3). A publicly-available version is in ADAMS under Accession No. ML16064A215; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

Provisional Operating License No. DPR–5 and Facility Operating License Nos. DPR–26 and DPR–64: The amendments revised the Provisional Operating License for Unit No. 1 and the Facility Operating Licenses for Unit Nos. 2 and 3.

Date of initial notice in ***Federal Register:*** August 4, 2015 (80 FR 46348).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated April 12, 2016.

No significant hazards consideration comments received: No.

Exelon Generation Company, LLC, Docket Nos. 50–317 and 50–318, Calvert Cliffs Nuclear Power Plant, Units 1 and 2, Calvert County, Maryland

Date of amendment request: November 5, 2015.

Brief description of amendments: The amendments revise the Surveillance Requirement (SR) frequencies for SRs 3.4.6.4, 3.4.7.4, 3.4.8.3, 3.5.2.10, 3.6.6.9, 3.9.4.2, and 3.9.5.4. The changes to the SR frequencies relocate the frequencies to the Surveillance Frequency Control Program.

Date of issuance: April 11, 2016.

Effective date: As of the date of issuance and shall be implemented within 60 days of issuance.

Amendment Nos.: 317 and 295. A publicly-available version is in ADAMS under Accession No. ML16060A401; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

Renewed Facility Operating License Nos. DPR–53 and DPR–69: Amendments revised the Renewed Facility Operating Licenses and Technical Specifications.

Date of initial notice in ***Federal Register:*** January 5, 2016 (81 FR 261).

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated April 11, 2016.

No significant hazards consideration comments received: No.

Exelon Generation Company, LLC, Docket No. 50–410, Nine Mile Point Nuclear Station, Unit 2, Oswego County, New York

Date of amendment request: March 23, 2015, as supplemented by letters dated January 8, 2016, and March 21, 2016.

Brief description of amendment: The amendment revised the technical specifications (TS) and relocated the secondary containment bypass leakage paths table from the TS to the Technical Requirements Manual.

Date of issuance: April 19, 2016.

Effective date: As of the date of issuance and shall be implemented within 120 days of issuance.

Amendment No.: 156. A publicly-available version is in ADAMS under Accession No. ML16088A053; documents related to this amendment is listed in the Safety Evaluation enclosed with the amendment.

Renewed Facility Operating License No. NPF–69: Amendment revised the Renewed Facility Operating License and TSs.

Date of initial notice in ***Federal Register:*** September 29, 2015 (80 FR 58517). The supplemental letters dated January 8, 2016, and March 21, 2016, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated April 19, 2016.

No significant hazards consideration comments received: No.

Florida Power & Light Company, et al., Docket No. 50–389, St. Lucie Plant, Unit No. 2 (PSL–2), St. Lucie County, Florida

Date of amendment request: December 30, 2014, as supplemented by letters dated March 23, June 2, June 18, July 30, October 2, November 3, 2015; and December 8, 2015.

Brief description of amendment: The amendment revised the Technical Specifications (TSs) to allow the use of AREVA fuel and AREVA M5® material as an approved fuel rod cladding at PSL–2.

Date of issuance: April 19, 2016.

Effective date: As of the date of issuance and shall be implemented upon the start of the PSL–2 Cycle 23 spring 2017 refueling outage to support the AREVA fuel transition project plan.

Amendment No.: 182. A publicly-available version is in ADAMS under Accession No. ML16063A121; documents related to this amendment are listed in the Safety Evaluation enclosed with the amendment.

Renewed Facility Operating License No. NPF–16: Amendment revised the Renewed Facility Operating License and TSs.

Date of initial notice in ***Federal Register:*** June 9, 2015 (80 FR 32620). The supplements dated June 2, June 18, July 30, October 2, November 3, and December 8, 2015, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated April 19, 2016.

No significant hazards consideration comments received: No.

Pacific Gas and Electric Company (PG&E), Docket Nos. 50–275 and 50–323, Diablo Canyon Nuclear Power Plant, Unit Nos. 1 and 2, San Luis Obispo County, California

Date of application for amendments: June 26, 2013, as supplemented by letters dated September 29, October 27, October 29, November 26, and December 31, 2014; February 25 (two letters), May 7, October 15, and December 31, 2015; and January 28, 2016.

Brief description of amendments: The amendments permit the PG&E (the licensee) to adopt a new fire protection licensing basis based on National Fire Protection Association (NFPA) Standard 805, "Performance-Based Standard for Fire Protection for Light Water Reactor Generating Plants (2001 Edition)," at Diablo Canyon Power Plant, Units 1 and 2, that complies with the requirements of 10 CFR 50.48(a) and (c) and the guidance in Revision 1 of Regulatory Guide 1.205, "Risk Informed Performance-Based Fire Protection for Existing Light-Water Nuclear Power Plants," December 2009.

Date of issuance: April 14, 2016.

Effective date: As of its date of issuance and shall be implemented as described in the transition license conditions.

Amendment Nos.: Unit 1—225; Unit 2—227. A publicly-available version is in ADAMS under Accession No. ML16035A441; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

Facility Operating License Nos. DPR–80 and DPR–82: The amendments revised the Facility Operating Licenses and Technical Specifications.

Date of initial notice in ***Federal Register***: December 26, 2013 (78 FR 78408). The supplemental letters dated October 3, 2013; September 29, October 27, October 29, November 26, and December 31, 2014; February 25 (two letters), May 7, October 15, and December 31, 2015; and January 28, 2016, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated April 14, 2016.

No significant hazards consideration comments received: No.

Southern Nuclear Operating Company, Docket Nos. 52–025 and 52–026, Vogtle Electric Generating Plant (VEGP), Units 3 and 4, Burke County, Georgia

Date of amendment request: September 1, 2015.

Brief description of amendment: The amendment authorized changes to the VEGP Units 3 and 4 plant specific emergency planning inspections, tests, analyses, and acceptance criteria (ITAAC) in Appendix C of VEGP Units 3 and 4 Combined Operating Licenses (COLs). The changes authorize the removal of the copy of Updated Final Safety Analysis Report Table 7.5–1, "Post-Accident Monitoring System" from ITAAC in Appendix C of the VEGP Units 3 and 4 COLs.

Date of issuance: March 30, 2016.

Effective date: As of the date of issuance and shall be implemented within 30 days of issuance.

Amendment No.: 47. A publicly-available version is in ADAMS under Accession No. ML16061A220; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

Facility Combined Licenses Nos. NPF–91 and NPF–92: Amendment revised the Facility Combined Licenses.

Date of initial notice in ***Federal Register***: October 27, 2015 (80 FR 65807).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated March 30, 2015.

No significant hazards consideration comments received: No.

Southern Nuclear Operating Company, Inc., Georgia Power Company, Oglethorpe Power Corporation, Municipal Electric Authority of Georgia, City of Dalton, Georgia, Docket Nos. 50–321 and 50–366, Edwin I. Hatch Nuclear Plant, Unit Nos. 1 and 2, Appling County, Georgia

Date of amendment request: January 13, 2015, as supplemented by letters dated June 16 and November 24, 2015.

Brief description of amendments: The amendments adopt Technical Specification Task Force change number 523, Revision 2, "Generic Letter 2008–01, Managing Gas Accumulation," for the Hatch Nuclear Plant, Unit Nos 1 and 2, technical specifications. The change revised or added surveillance requirements to verify that the system locations susceptible to gas accumulation are sufficiently filled with water and to provide allowances which permit performance of the verification.

Date of issuance: April 14, 2016.

Effective date: As of the date of issuance and shall be implemented within 120 days of issuance.

Amendment Nos.: 278 and 222. A publicly-available version is in ADAMS under Accession No. ML16090A174; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

Facility Operating License Nos. DPR–57 and NPF–5: Amendments revised the Facility Operating Licenses and Technical Specifications.

Date of initial notice in ***Federal Register***: March 17, 2015 (80 FR 13911). The supplemental letters dated June 16 and November 24, 2015, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated April 14, 2016.

No significant hazards consideration comments received: No.

Wolf Creek Nuclear Operating Corporation, Docket No. 50–482, Wolf Creek Generating Station, Coffey County, Kansas

Date of amendment request: September 23, 2015.

Brief description of amendment: The amendment revised the diesel generator (DG) full load rejection test and endurance and margin test specified by Technical Specification (TS) 3.8.1, "AC [Alternating Current] Sources—Operating," Surveillance Requirements (SR) 3.8.1.10 and 3.8.1.14, respectively. The change adds a new Note to SR 3.8.1.10 and SR 3.8.1.14, consistent with Technical Specification Task Force (TSTF) traveler TSTF–276–A, Revision 2, "Revise DG full load rejection test." The Note allows the full load rejection test and endurance and margin test to be performed at the specified power factor with clarifications addressing situations when the power factor cannot be achieved.

Date of issuance: April 15, 2016.

Effective date: As of its date of issuance and shall be implemented within 90 days of issuance.

Amendment No.: 215. A publicly-available version is in ADAMS under Accession No. ML16081A194; documents related to this amendment are listed in the Safety Evaluation enclosed with the amendment.

Renewed Facility Operating License No. NPF–42. The amendment revised the Operating License and Technical Specifications.

Date of initial notice in ***Federal Register***: November 24, 2015 (80 FR 73242).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated April 15, 2016.

No significant hazards consideration comments received: No.

Dated at Rockville, Maryland, this 2nd day of May 2016.

For the Nuclear Regulatory Commission.

Anne T. Boland,

Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2016–10949 Filed 5–9–16; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–391; NRC–2008–0369]

Issuance of Operating License and Record of Decision; Tennessee Valley Authority; Watts Bar Nuclear Plant, Unit 2

AGENCY: Nuclear Regulatory Commission.

ACTION: Operating license and record of decision; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has issued operating license No. NPF–96 to Tennessee Valley Authority (TVA), the operator of Watts Bar Nuclear Plant (WBN), Unit 2. Operating license No. NPF–96 authorizes full power operation of WBN, Unit 2. In addition, the NRC has prepared a Record of Decision (ROD) that supports the NRC's decision to issue operating license No. NPF–96.

DATES: Operating license No. NPF–96 was effective on October 22, 2015.

ADDRESSES: Please refer to Docket ID NRC–2008–0369 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2008–0369. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select "*ADAMS Public Documents*" and then select "*Begin Web-based ADAMS Search.*" For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* For the convenience of the reader, the ADAMS accession numbers are provided in a table in the "Availability of Documents" section of this document.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Robert Schaaf, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–6020; email: *Robert.Schaaf@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

Notice is hereby given that the NRC issued operating license No. NPF–96 to TVA, the operator of WBN, Unit 2. Operating license No. NPF–96 authorizes full power operation of WBN, Unit 2. The NRC's ROD that supports its decision to issue operating license No. NPF–96 is available in ADAMS. The NRC staff's safety analysis of TVA's application for the operating license is documented in NUREG–0847, "Safety Evaluation Report Related to the Operation of Watts Bar Nuclear Plant, Units 1 and 2", as supplemented through Supplement 29. The NRC staff's updated assessment of the environmental impacts of operation is documented in NUREG–0498, "Final Environmental Statement Related to the Operation of Watts Bar Nuclear Plant, Unit 2," Supplement 2. The NRC finds that the updated application for the operating license filed by TVA on March 4, 2009, complies with the requirements of the Atomic Energy Act of 1954, as amended, and the NRC's regulations.

The NRC originally intended for this notice to be published in the **Federal Register**immediately following issuance of the WBN, Unit 2, operating license on October 22, 2015; however, during recent verification of operating license documentation the NRC identified that the notice had not been forwarded to the Office of the Federal Register for publication as intended.

II. Further Information

The NRC prepared a "Safety Evaluation Report Related to the Operation of Watts Bar Nuclear Plant, Units 1 and 2" (NUREG–0847), that was published in June 1982, and Supplements 1 through 29 that were published between September 1982 and October 2015. In Supplements 1 through 20 the NRC staff concluded that WBN, Unit 1, met all applicable regulations and regulatory guidance. In Supplement 21, the NRC staff reported on the WBN, Unit 2, open items remaining to be resolved, which were outstanding at the time that TVA deferred construction of WBN, Unit 2. In Supplements 22 through 29, the NRC staff documented its evaluation and closure of the open items in response to TVA's updated application for a license to operate WBN Unit 2, filed on March 4, 2009. The NRC staff also prepared a "Final Environmental Statement Related to the Operation of Watts Bar Nuclear Plant, Unit 2" (NUREG–0498), Supplement 2, dated May 2013. NUREG–0847 and its supplements and NUREG–0498, Supplement 2, document the information reviewed and the NRC's conclusions. The NRC also prepared a ROD in accordance with the Commission's regulations to accompany its action on the operating license application. The ROD incorporates by reference the materials contained in NUREG–0498, Supplement 2.

III. Availability of Documents

The documents identified in the following table are available to interested persons, as indicated.

Document	ADAMS accession No.
"Watts Bar Nuclear Plant (WBN) Unit 2—Operating License Application Update".	ML090700378.

Document	ADAMS accession No.
"Safety Evaluation Report Related to the Operation of Watts Bar Nuclear Plant, Units 1 and 2" (NUREG–0847), and Supplement 21 through Supplement 29.	ML072060490, ML072060500, ML072060518, ML072060520, ML072060524, ML072060527, ML072060464, ML072060471, ML072060478, ML072060469, ML072060473, ML072060476, ML072060479, ML072060484, ML072060486, ML072060488, ML072060493, ML072060496, ML070530364, ML070530539, ML072060498, ML090570741, ML110390197, ML11206A499, ML11277A148, ML12011A024, ML13205A136, ML15033A041, ML15229A195, ML15282A051.
"Final Environmental Statement Related to the Operation of Watts Bar Nuclear Plant, Unit 2" (NUREG–0498), Supplement 2.	ML13144A092.
Letter transmitting Operating License No. NPF–96 and accompanying documentation.	ML15251A587.
Record of Decision	ML15257A130.

Dated at Rockville, Maryland, this 27th day of April 2016.

For the Nuclear Regulatory Commission.

Anne T. Boland,

Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2016–10950 Filed 5–9–16; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2016–0001]

Sunshine Act Meeting Notice

DATE: May 9, 16, 23, 30, June, 6, 13, 2016.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

Week of May 9, 2016

There are no meetings scheduled for the week of May 9, 2016.

Week of May 16, 2016—Tentative

Tuesday, May 17, 2016

9:00 a.m.—Briefing on the Status of Lessons Learned from the Fukushima Dai-ichi Accident (Public Meeting) (Contact: Kevin Witt: 301–415–2145)

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

Thursday, May 19, 2016

10:00 a.m.—Briefing on Security Issues (Closed Ex. 1)

1:30 p.m.—Briefing on Security Issues (Closed Ex. 1)

Week of May 23, 2016—Tentative

There are no meetings scheduled for the week of May 23, 2016.

Week of May 30, 2016—Tentative

Wednesday, June 1, 2016

9:00 a.m.—Briefing on Security Issues (Closed Ex. 1)

Thursday, June 2, 2016

9:00 a.m.—Briefing on Results of the Agency Action Review Meeting (Public Meeting) (Contact: Andrew Waugh: 301–415–5601)

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

2:00 p.m.—Discussion of Management and Personnel Issues (Closed—Ex. 2 & 6)

Week of June 6, 2016—Tentative

There are no meetings scheduled for the week of June 6, 2016.

Week of June 13, 2016—Tentative

There are no meetings scheduled for the week of June 13, 2016.

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The schedule for Commission meetings is subject to change on short notice. For more information or to verify the status of meetings, contact Denise McGovern at 301–415–0681 or via email at *Denise.McGovern@nrc.gov.*

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The NRC Commission Meeting Schedule can be found on the Internet at:*http://www.nrc.gov/public-involve/public-meetings/schedule.html.*

* * * * *

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.* braille, large print), please notify Kimberly Meyer, NRC Disability Program Manager, at 301–287–0739, by videophone at 240–428–3217, or by email at *Kimberly.Meyer-Chambers@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

* * * * *

Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555 (301–415–1969), or email *Brenda.Akstulewicz@nrc.gov* or *Patricia.Jimenez@nrc.gov.*

Dated: May 5, 2016.

Denise McGovern,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2016–11020 Filed 5–6–16; 11:15 am]

BILLING CODE 7590–01–P

OVERSEAS PRIVATE INVESTMENT CORPORATION

Sunshine Notice—June 1, 2016 Public Hearing

TIME AND DATE: 2:00 p.m., Wednesday, June 1, 2016.

PLACE: Offices of the Corporation, Twelfth Floor Board Room, 1100 New York Avenue NW., Washington, DC.

STATUS: Hearing OPEN to the Public at 2:00 p.m.

PURPOSE: Public Hearing in conjunction with each meeting of OPIC's Board of Directors, to afford an opportunity for any person to present views regarding the activities of the Corporation.

PROCEDURES: Individuals wishing to address the hearing orally must provide advance notice to OPIC's Corporate Secretary no later than 5 p.m. Wednesday, May 25, 2016. The notice must include the individual's name, title, organization, address, and telephone number, and a concise summary of the subject matter to be presented.

Oral presentations may not exceed ten (10) minutes. The time for individual presentations may be reduced proportionately, if necessary, to afford all participants who have submitted a timely request an opportunity to be heard.

Participants wishing to submit a written statement for the record must submit a copy of such statement to OPIC's Corporate Secretary no later than 5 p.m. Wednesday, May 25, 2016. Such statement must be typewritten, double spaced, and may not exceed twenty-five (25) pages.

Upon receipt of the required notice, OPIC will prepare an agenda, which will be available at the hearing, that identifies speakers, the subject on which each participant will speak, and the time allotted for each presentation.

A written summary of the hearing will be compiled, and such summary will be made available, upon written request to OPIC's Corporate Secretary, at the cost of reproduction.

Written summaries of the projects to be presented at the June 9, 2016 Board meeting will be posted on OPIC's Web site.

CONTACT PERSON FOR INFORMATION: Information on the hearing may be obtained from Catherine F. I. Andrade at (202) 336–8768, via facsimile at (202) 408–0297, or via email at *Catherine.Andrade@opic.gov.*

Dated: May 6, 2016.

Catherine F. I. Andrade,

OPIC Corporate Secretary.

[FR Doc. 2016–11058 Filed 5–6–16; 4:15 pm]

BILLING CODE 3210–01–P

RAILROAD RETIREMENT BOARD

Proposed Collection; Comment Request

Summary: In accordance with the requirement of Section 3506 (c)(2)(A) of the Paperwork Reduction Act of 1995 which provides opportunity for public comment on new or revised data collections, the Railroad Retirement Board (RRB) will publish periodic summaries of proposed data collections.

Comments are invited on: (a) Whether the proposed information collection is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the RRB's estimate of the burden of the collection of the information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden related to the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

1. Title and purpose of information collection: Repayment of Debt; OMB 3220–0169. When the Railroad Retirement Board (RRB) determines that an overpayment of Railroad Retirement Act or Railroad Unemployment Insurance Act benefits has occurred, it initiates prompt action to notify the annuitant of the overpayment and to recover the money owed the RRB. To effect payment of a debt by credit card, the RRB utilizes Form G–421F, Repayment by Credit Card. The RRB's procedures pertaining to benefit overpayment determinations and the recovery of such benefits are prescribed in 20 CFR 255 and 340.

One form is completed by each respondent. Completion is voluntary. The RRB proposes no changes to Form G–421F.

ESTIMATE OF ANNUAL RESPONDENT BURDEN

Form No.	Annual responses	Time (minutes)	Burden (hours)
G–421F	535	5	45
Total	535	....	45

Additional Information or Comments: To request more information or to obtain a copy of the information collection justification, forms, and/or supporting material, contact Dana Hickman at (312) 751–4981 or *Dana.Hickman@RRB.GOV.* Comments regarding the information collectiaon should be addressed to Charles Mierzwa, Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois 60611–2092 or emailed to *Charles.Mierzwa@RRB.GOV.* Written comments should be received within 60 days of this notice.

Charles Mierzwa,

Chief of Information Resources Management.

[FR Doc. 2016–10926 Filed 5–9–16; 8:45 am]

BILLING CODE 7905–01–P

SECURITIES AND EXCHANGE COMMISSION

[File No. 500–1]

In the Matter of Code Rebel Corporation; Order of Suspension of Trading

May 6, 2016.

It appears to the Securities and Exchange Commission that there is a lack of accurate information concerning the securities of Code Rebel Corporation ("CDRB") because of questions regarding the accuracy of statements in CDRB's Forms 10–Q for the quarters ended June 30, 2015 and September 30, 2015, and the Form 10–K for the year ending December 31, 2015, concerning the company's assets and financial condition. CDRB is a Delaware corporation with its principal executive offices in Kahului, Hawaii. Its stock is listed on NASDAQ under the symbol CDRB.

The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of the above-listed company.

Therefore, it is ordered, pursuant to Section 12(k) of the Securities Exchange Act of 1934, that trading in the securities of the above-listed company is suspended for the period from 9:30 a.m. EDT on May 6, 2016, through 11:59 p.m. EDT on May 19, 2016.

By the Commission.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2016–11067 Filed 5–6–16; 4:15 pm]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–77765; File No. SR–NASDAQ–2016–033]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1, Relating to the Exchange's Offering of Remote ITCH to Trade Options Wave Ports

May 4, 2016.

I. Introduction

On March 2, 2016, The Nasdaq Stock Market LLC ("Exchange" or "Nasdaq") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder,[2] a proposed rule change to offer Remote ITCH to Trade Options ("ITTO") Wave Ports and to establish fees for this new optional wireless connectivity service. The proposed rule change was published for comment in the **Federal Register** on March 22, 2016.[3] On April 25, 2016, the Exchange filed Amendment No. 1 to the proposed rule change.[4] The Commission received no comments on this proposed rule change. The Commission is publishing this notice to solicit comments on Amendment No. 1 from interested persons, and is approving the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.

II. Description of the Proposal, as Modified by Amendment No. 1

The Exchange currently provides Nasdaq ITTO market data through fiber optic networks.[5] The Exchange now proposes to also provide this data through wireless networks, which experience lower latency than fiber optic networks. Specifically, the Exchange proposes to offer Remote ITTO Wave Ports[6] for clients co-located at third-party data centers in Mahwah, NJ and Secaucus, NJ, through which Nasdaq ITTO market data will be distributed after delivery to those data centers via a wireless network, and to establish fees for these Remote ITTO Wave Ports.[7]

The Exchange proposes a $5,000 installation fee for a Remote ITTO Wave Port in Mahwah and a $2,500 installation fee for a Remote ITTO Wave Port in Secaucus.[8] The Exchange also proposes a $10,000 recurring monthly fee for a Remote ITTO Wave Port in Mahwah and a $7,500 recurring monthly fee for a Remote ITTO Wave Port in Secaucus.[9] Clients who choose to subscribe to a Remote ITTO Wave Port will continue to be liable for the Nasdaq ITTO market data fees set forth in NOM Rule Chapter XV, Section 4(a).

In addition, the Exchange proposes to provide new clients of this service a 30-day testing period during which the Exchange will waive the recurring monthly fees.[10] During the 30-day testing period, a client may cancel its subscription, but will forfeit the installation fee.[11] If a client does not cancel its subscription prior to the end of the 30-day testing period, a one-year minimum purchase period will begin.[12]

III. Discussion and Commission Findings

After careful review, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[13] In particular, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with Section 6(b)(4) of the Act,[14] which requires that the rules of a national securities exchange provide for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities, and with Section 6(b)(5) of the Act,[15] which requires, among other things, that the rules of a national securities exchange be designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest, and not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers. In addition, the Commission finds that the proposed rule change is consistent with Section 6(b)(8) of the Act,[16] which requires that the rules of the exchange not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

The Commission believes that the proposed rule change is consistent with Section 6(b)(4) of the Act.[17] Under the proposal, all clients that voluntarily select the wireless connectivity service will be charged the same amount for the same services.[18] The Commission also notes that, according to the Exchange, the proposed fees are reasonable because they are based on costs to cover hardware, installation, testing, and connection, as well as expenses involved in maintaining and managing the connection. The Exchange states that these fees would allow it to recoup costs and make a profit, and would reflect the value provided to clients as a result of the lower latency. The Exchange states that the costs associated with the wireless connectivity system are incrementally higher than fiber optics-based solutions due to the expense of the wireless equipment, cost of installation, and testing. The Exchange also states that the differences between the fees for Mahwah and Secaucus reflect the higher cost of connecting to Mahwah because of the longer distance to Mahwah, as well as the higher cost for co-locating and connecting within Mahwah. As noted above, the Remote ITTO Wave Port fees are subject to a 30-day testing period during which the recurring monthly fees are waived, and a one-year minimum purchase period that begins at the conclusion of the 30-day testing period.[19] The Exchange notes that the proposed waiver process is the same as the existing waiver process for Remote MITCH Wave Ports under Nasdaq Rule 7015(g)(1) and is intended as an incentive to clients, and that the one-year minimum purchase period is common practice for co-location offerings that allows the Exchange to recoup the substantial investment required to establish the wireless system.[20]

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 77381 (March 16, 2016), 81 FR 15394.

[4] In Amendment No. 1, which amended and replaced the original filing in its entirety, the Exchange: (i) clarified that there will be a one-year minimum purchase period for Remote ITTO Wave Ports, which will begin at the conclusion of the 30-day testing period; (ii) clarified that the Exchange will only waive the recurring monthly fee during the 30-day testing period; and (iii) made other technical changes to the proposed rule change. Amendment No. 1 is available at: *http://www.sec.gov/comments/sr-nasdaq-2016-033/nasdaq2016033-1.pdf*.

[5] Nasdaq ITTO is a data feed that provides quotation information for individual orders on the Nasdaq Options Market ("NOM") book, last sale information for trades executed on NOM, and order imbalance information. *See* NOM Rule Chapter VI, Section 1(a)(3)(A).

[6] According to the Exchange, a Remote Wave Port is a physical port located in Nasdaq's space within a third-party's data center that receives market data delivered by Nasdaq via its wireless network, which is then simultaneously distributed to Wave Ports within that location.

[7] The Exchange notes that it currently offers a similar service for TotalView ITCH equities market data through Remote MITCH Wave Ports located in Mahwah and Secaucus. *See* Nasdaq Rule 7015(g)(1). According to the Exchange, it recently increased the capacity of its wireless networks connecting Nasdaq's Carteret data center to these third-party data centers, so they may now support the delivery of ITTO market data.

[8] *See* proposed NOM Rule Chapter VX, Section 3(c).

[9] *See id.*

[10] *See id.* The Exchange will not waive the installation fee or the Nasdaq ITTO market data fees during this testing period. *See* Amendment No. 1, *supra* note 4.

[11] *See* Amendment No. 1, *supra* note 4.

[12] *See* proposed NOM Rule Chapter VX, Section 3(c) and Amendment No. 1, *supra* note 4.

[13] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[14] 15 U.S.C. 78f(b)(4).

[15] 15 U.S.C. 78f(b)(5).

[16] 15 U.S.C. 78f(b)(8).

[17] 15 U.S.C. 78f(b)(4).

[18] The Commission notes that the proposed fees are identical to the fees for Remote MITCH Wave Ports located in the same third-party data centers in Mahwah and Secaucus. *See* Nasdaq Rule 7015(g)(1).

The Commission believes that the proposed rule change is consistent with Section 6(b)(5) of the Act.[21] As noted above, the proposal would make available an optional, low latency method to receive Nasdaq ITTO market data at third-party data centers. Also as noted above, the Exchange already offers TotalView ITCH equities market data through Remote MITCH Wave Ports for clients co-located at third-party data centers in Mahwah and Secaucus. Moreover, the Commission believes that the proposal is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers because all co-located clients will have the option to voluntarily select the wireless connectivity service, there is no differentiation among clients with respect to the fees charged for the service, and the latency reduction will be the same for all clients who choose this service.

The Commission also believes that the proposed rule change is consistent with Section 6(b)(8) of the Act.[22] According to the Exchange, if it charges excessive fees for co-location or connectivity services, affected members could opt to terminate their co-location and/or connectivity services and adopt a possible range of alternative strategies, including, for example, using another vendor for connectivity services or pursuing trading strategies not dependent upon co-location, and this would negatively impact the Exchange's co-location, connectivity, and trading revenues. The Exchange also notes that wireless technology has been in use for decades, is available from multiple providers, and has been adopted by other exchanges to offer wireless connectivity for delivery of market data. Moreover, Nasdaq ITTO market data will continue to be available through fiber optic networks.

For the foregoing reasons, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with the Act.

IV. Solicitation of Comments on Amendment No. 1

Interested persons are invited to submit written data, views, and arguments concerning whether Amendment No. 1 is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File No. SR–NASDAQ–2016–033 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File No. SR–NASDAQ–2016–033. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–NASDAQ–2016–033 and should be submitted on or before May 31, 2016.

V. Accelerated Approval of Proposed Rule Change, as Modified by Amendment No. 1

The Commission finds good cause to approve the proposed rule change, as modified by Amendment No. 1, prior to the thirtieth day after the date of publication of Amendment No. 1 in the **Federal Register**. Amendment No. 1 provided clarification and additional information to the proposed rule change, and did not raise any novel regulatory issues. In particular, Amendment No. 1 stated that there will be a one-year minimum purchase period for Remote ITTO Wave Ports, which will begin at the conclusion of the 30-day testing period, and stated that the Exchange will only waive the recurring monthly fee during the 30-day testing period.[23] As noted above, the Exchange states that the proposed waiver process is the same as the existing waiver process for Remote MITCH Wave Ports under Nasdaq Rule 7015(g)(1), and that the one-year minimum purchase period is common practice for co-location offerings.[24] Accordingly, the Commission finds good cause, pursuant to Section 19(b)(2) of the Act,[25] to approve the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.

VI. Conclusion

IT IS THEREFORE ORDERED, pursuant to Section 19(b)(2) of the Act,[26] that the proposed rule change (SR–NASDAQ–2016–033), as modified by Amendment No.1, be, and hereby is, approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[27]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–10885 Filed 5–9–16; 8:45 am]

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[19] *See supra* notes 10–12 and accompanying text.

[20] *See* Amendment No.1, *supra* note 4. *See also* BX Rule 7015 (stating that Remote MITCH Wave Port fees are subject to a 30-day testing period during which the otherwise applicable fees are waived, and a one-year minimum purchase period).

[21] 15 U.S.C. 78f(b)(5).

[22] 15 U.S.C. 78f(b)(8).

[23] *See* Amendment No. 1, *supra* note 4.

[24] *See supra* note 20 and accompanying text.

[25] 15 U.S.C. 78s(b)(2).

[26] *See id.*

[27] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. IC–32106; File No. 812–14429]

Triloma EIG Global Energy Fund, et al.; Notice of Application

May 5, 2016.

AGENCY: Securities and Exchange Commission ("Commission").

ACTION: Notice of application for an order under sections 17(d) and 57(i) of the Investment Company Act of 1940 (the "Act") and rule 17d–1 under the Act to permit certain joint transactions otherwise prohibited by sections 17(d) and 57(a)(4) of the Act and rule 17d–1 under the Act.

SUMMARY OF APPLICATION: Applicants request an order to permit certain business development companies ("BDC") and closed-end management investment companies to co-invest in portfolio companies with each other and with affiliated investment funds.

APPLICANTS: Triloma EIG Global Energy Fund (the "Perpetual Fund"), Triloma EIG Global Energy Term Fund I (the "Term Fund" and, together with the Perpetual Fund, the "Existing Regulated Entities"); Triloma Energy Advisors, LLC ("Triloma"); EIG Credit Management Company, LLC ("EIG"); EIG Asset Management, LLC, EIG Funds Management, LLC, EIG Management Company, LLC, EIG Global Energy (Asia) Limited, EIG Harbour Energy Advisor, L.P. (collectively, together with EIG, the "Existing EIG Advisors"); EIG-Gateway Direct Investments, L.P., EIG Energy Fund XVI, L.P., EIG Energy Fund XVI–B, L.P., EIG Energy Fund XVI–E, L.P., EIG Energy Fund XVI (Cayman), L.P., EIG Energy Fund XVI (Scotland), L.P., EIG-Keats Energy Partners, L.P., EIG Global Private Debt Fund-A, L.P., EIG Global Private Debt Fund-A (UL), L.P., EIG Global Private Debt Sub Fund-B, L.P., EIG Global Private Debt Sub B (UL), L.P., EIG Global Private Debt Finco-B, LLC, EIG Global Private Debt Finco-B (UL), LLC, and Harbour Energy Ltd. (collectively, the "Existing Affiliated Investors").

FILING DATES: The application was filed on March 6, 2015, and amended on November 12, 2015, February 24, 2016, and April 29, 2016.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on May 27, 2016, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, U.S. Securities and Exchange Commission, 100 F St. NE., Washington, DC 20549–1090. Applicants: Triloma and the Existing Regulated Entities: 201 N. New York Avenue, Suite 250, Winter Park, FL 32789; the Existing EIG Advisors and the Existing Affiliated Investors: 1700 Pennsylvania Ave. NW., Suite 800, Washington, DC 20006.

FOR FURTHER INFORMATION CONTACT: Robert Shapiro, Senior Counsel, at (202) 551–7758 or Mary Kay Frech, Branch Chief, at (202) 551–6821 (Chief Counsel's Office, Division of Investment Management).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Applicants' Representations

1. Term Fund was organized under the Delaware Statutory Trust Act for the purpose of operating as an externally-managed, non-diversified, closed-end management investment company. Term Fund is a registered investment company under the Act. Term Fund's Objectives and Strategies[1] are to provide shareholders with current income, capital preservation and, to a lesser extent, long-term capital appreciation by investing primarily in a global portfolio of privately originated energy company and project debt. Term Fund has a five member Board,[2] of which three members are Independent Trustees,[3] one member is considered an "interested person" of Triloma, within the meaning of section 2(a)(19) of the Act, and one member is considered an "interested person" of EIG.

2. Perpetual Fund was organized under the Delaware Statutory Trust Act for the purpose of operating as an externally-managed, non-diversified, closed-end management investment company. Perpetual Fund is a registered investment company under the Act. Perpetual Fund has the same Objectives and Strategies as Term Fund. Perpetual Fund will be governed by a Board comprised of the same trustees (including Independent Trustees) that serve as the Board of Term Fund.

3. Triloma is a Florida limited liability company and is registered as an investment adviser under the Investment Advisers Act of 1940 (the "Advisers Act"). Triloma serves as the investment adviser to the Existing Regulated Entities. Triloma also provides administrative services to the Existing Regulated Entities under an administrative services agreement.

4. EIG is a Delaware limited liability company and is registered as an investment adviser under the Advisers Act. EIG serves as the sub-adviser to the Existing Regulated Entities. EIG is an indirectly owned subsidiary of EIG Global Energy Partners, LLC ("EIG Partners").

5. Each Existing Affiliated Investors is a privately-offered fund that would be an investment company but for section 3(c)(1) or 3(c)(7) of the Act. An Existing EIG Advisor serves as the investment adviser to each Existing Affiliated Investor. Each Existing EIG Advisor is either, directly or indirectly, controlled by EIG Partners or under common control with EIG and is registered as an investment adviser under the Advisers Act.

6. Applicants seek an order ("Order") to permit one or more Regulated Entities[4] and/or one or more Affiliated

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[1] "Objectives and Strategies" means a Regulated Entity's (as defined below) investment objectives and strategies, as described in the Regulated Entity's registration statement on Form N–2, other filings the Regulated Entity has made with the Commission under the Securities Act of 1933 (the "Securities Act"), or under the Securities Exchange Act of 1934, and the Regulated Entity's reports to shareholders.

[2] The term "Board" refers to the board of directors or trustees of any Regulated Entity.

[3] The term "Independent Trustees" refers to the trustees or directors of any Regulated Entity that are not "interested persons" of the Regulated Entity within the meaning of section 2(a)(19) of the Act.

[4] "Regulated Entity" means any of the Existing Regulated Entities and any Future Regulated Entity. "Future Regulated Entity" means a closed-end management investment company (a) that is registered under the Act or has elected to be regulated as a BDC under the Act, (b) whose investment adviser is a Triloma Advisor and (c) whose investment sub-adviser is an EIG Advisor. "Triloma Advisor" means Triloma or any future investment adviser that (i) controls, is controlled by or is under common control with Triloma, (ii) is registered as an investment adviser under the Advisers Act and (iii) is not a Regulated Entity or a subsidiary of a Regulated Entity. "EIG Advisor" means any Existing EIG Advisor or any future investment adviser that (i) controls, is controlled by or is under common control with EIG, (ii) is registered as an investment adviser under the Advisers Act, and (iii) is not a Regulated Entity or a subsidiary of a Regulated Entity.

Investors[5] to participate in the same investment opportunities through a proposed co-investment program (the "Co-Investment Program") where such participation would otherwise be prohibited under sections 17(d) and 57(a)(4) and the rules under the Act. For purposes of the application, "Co-Investment Transaction" means any transaction in which a Regulated Entity (or its Wholly-Owned Investment Subsidiary, as defined below) participated together with one or more other Regulated Entities and/or one or more Affiliated Investors in reliance on the requested Order. "Potential Co-Investment Transaction" means any investment opportunity in which a Regulated Entity (or its Wholly-Owned Investment Subsidiary) could not participate together with one or more Affiliated Investors and/or one or more other Regulated Entities without obtaining and relying on the Order.[6] The term "Advisor" means any Triloma Advisor or any EIG Advisor.

7. Applicants state that a Regulated Entity may, from time to time, form a Wholly-Owned Investment Subsidiary.[7] Such a subsidiary would be prohibited from investing in a Co-Investment Transaction with any Affiliated Investor because it would be a company controlled by its parent Regulated Entity for purposes of section 57(a)(4) and rule 17d–1. Applicants request that each Wholly-Owned Investment Subsidiary be permitted to participate in Co-Investment Transactions in lieu of its parent Regulated Entity and that the Wholly-Owned Investment Subsidiary's participation in any such transaction be treated, for purposes of the requested Order, as though the parent Regulated Entity were participating directly. Applicants represent that this treatment is justified because a Wholly-Owned Investment Subsidiary would have no purpose other than serving as a holding vehicle for the Regulated Entity's investments and, therefore, no conflicts of interest could arise between the Regulated Entity and the Wholly-Owned Investment Subsidiary. The Regulated Entity's Board would make all relevant determinations under the conditions with regard to a Wholly-Owned Investment Subsidiary's participation in a Co-Investment Transaction, and the Regulated Entity's Board would be informed of, and take into consideration, any proposed use of a Wholly-Owned Investment Subsidiary in the Regulated Entity's place. If the Regulated Entity proposes to participate in the same Co-Investment Transaction with any of its Wholly-Owned Investment Subsidiaries, the Board will also be informed of, and take into consideration, the relative participation of the Regulated Entity and the Wholly-Owned Investment Subsidiary.

8. It is anticipated that an EIG Advisor will periodically determine that certain investments the EIG Advisor recommends for a Regulated Entity would also be appropriate investments for one or more other Regulated Entities and/or one or more Affiliated Investors. Such a determination may result in the Regulated Entity, one or more other Regulated Entities and/or one or more Affiliated Investors co-investing in certain investment opportunities. For each such investment opportunity, the Advisors to each Regulated Entity will independently analyze and evaluate the investment opportunity as to its appropriateness for such Regulated Entity taking into consideration the Regulated Entity's Objectives and Strategies.

9. Applicants state that Triloma serves as the Existing Regulated Entities' investment adviser and administrator and either it or another Triloma Advisor will serve in the same capacity to any Future Regulated Entity, and that EIG serves as the Existing Regulated Entities' sub-adviser and either it or another EIG Advisor will serve in the same capacity to any Future Regulated Entity. Applicants represent that although an EIG Advisor will identify and recommend investments[8] for each Regulated Entity, prior to any investment by the Regulated Entity, the EIG Advisor will present each proposed investment to the Triloma Advisor which has the authority to approve or reject all investments proposed for the Regulated Entity by the EIG Advisor.

10. Applicants state that each EIG Advisor has (or will have, in the case of future advisers) an investment committee through which it will carry out its obligation under condition 1 to make a determination as to the appropriateness of a Potential Co-Investment Transaction for each Regulated Entity. Applicants represent that each EIG Advisor, as a registered investment adviser, has (or will have, in the case of future advisers) developed a robust allocation process that is designed to allocate investment opportunities fairly and equitably among its clients over time. Applicants state that, in the case of a Potential Co-Investment Transaction, the applicable EIG Advisor would apply its allocation policies and procedures in determining the proposed allocation for the Regulated Entity consistent with the requirements of condition 2(a).

11. Applicants state that, once the applicable EIG Advisor determined a proposed allocation for a Regulated Entity, such EIG Advisor would notify the applicable Triloma Advisor of the Potential Co-Investment Transaction and the EIG Advisor's recommended allocation for such Regulated Entity. Applicants further state that the applicable Triloma Advisor would then present the Potential Co-Investment Transaction and the EIG Advisor's proposed allocation to the Triloma Advisor's investment committee for its approval. Applicants represent that the Triloma Advisor's investment committee would review the EIG Advisor's recommendation for the Regulated Entity and would have the ability to ask questions of the EIG Advisor and request additional information from the EIG Advisor. Applicants further submit that if the Triloma Advisor's investment committee approved the investment for the Regulated Entity, the investment and all relevant allocation information would then be presented to the Regulated Entity's Board for its approval in accordance with the conditions to the application. Applicants state that they believe the investment process between the EIG Advisors and the Triloma Advisors, prior to seeking approval from

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[5] "Affiliated Investors" means the Existing Affiliated Investors and any Future Affiliated Investor. "Future Affiliated Investor" means an entity (a) whose investment adviser is an EIG Advisor and (b) that would be an investment company but for section 3(c)(1) or 3(c)(7) of the Act.

[6] All existing entities that currently intend to rely upon the requested Order have been named as applicants. Any other existing or future entity that subsequently relies on the Order will comply with the terms and conditions of the application.

[7] The term "Wholly-Owned Investment Subsidiary" means an entity (i) that is wholly-owned by a Regulated Entity (with such Regulated Entity at all times holding, beneficially and of record, 100% of the voting and economic interests); (ii) whose sole business purpose is to hold one or more investments on behalf of the Regulated Entity (and, in the case of an entity that is licensed by the Small Business Administration to operate under the Small Business Investment Act of 1958, as amended (the "SBA Act"), as a small business investment company (an "SBIC"), to maintain a license under the SBA Act and issue debentures guaranteed by the Small Business Administration); (iii) with respect to which the Regulated Entity's Board has the sole authority to make all determinations with respect to the entity's participation under the conditions of the application; and (iv) that would be an investment company but for section 3(c)(1) or 3(c)(7) of the Act. All subsidiaries participating in the Co-Investment Program will be Wholly-Owned Investment Subsidiaries and will have Objectives and Strategies that are either substantially the same as, or a subset of, their parent Regulated Entity's Objectives and Strategies. A subsidiary that is an SBIC may be a Wholly-Owned Investment Subsidiary if it satisfies the conditions in this definition.

[8] Applicants represent that the Triloma Advisors will not source any Potential Co-Investment Transactions under the requested Order.

the Regulated Entity's Board (which is in addition to, rather than in lieu of, the procedures required under the conditions of the application), is significant and provides for additional procedures and processes to ensure that the Regulated Entity is being treated fairly in respect of Potential Co-Investment Transactions.

12. If the Advisors to a Regulated Entity determine that a Potential Co-Investment Opportunity is appropriate for the Regulated Entity (and the applicable Triloma Advisor approves the investment for such Regulated Entity), and one or more other Regulated Entities and/or one or more Affiliated Investors may also participate, the Advisors will present the investment opportunity to the Eligible Trustees[9] of the Regulated Entity prior to the actual investment by the Regulated Entity. As to any Regulated Entity, a Co-Investment Transaction will be consummated only upon approval by a required majority of the Eligible Trustees of such Regulated Entity within the meaning of section 57(o) of the Act ("Required Majority").[10]

13. With respect to the pro rata dispositions and follow-on Investments provided in conditions 7 and 8, a Regulated Entity may participate in a pro rata disposition or follow-on Investment without obtaining prior approval of the Required Majority if, among other things: (i) The proposed participation of each Regulated Entity and Affiliated Investor in such disposition is proportionate to its outstanding investments in the issuer immediately preceding the disposition or follow-on investment, as the case may be; and (ii) each Regulated Entity's Board has approved that Regulated Entity's participation in pro rata dispositions and follow-on investments as being in the best interests of the Regulated Entity. If the Board does not so approve, any such disposition or follow-on investment will be submitted to the Regulated Entity's Eligible Trustees. The Board of any Regulated Entity may at any time rescind, suspend or qualify its approval of pro rata dispositions and follow-on investments with the result that all dispositions and/or follow-on investments must be submitted to the Eligible Trustees.

14. No Independent Trustee of a Regulated Entity will have a financial interest in any Co-Investment Transaction.

15. Under condition 15, if an Advisor or its principals, or any person controlling, controlled by, or under common control with the Advisor or its the principals, and any Affiliated Investors (collectively, the "Holders") own in the aggregate more than 25% of the outstanding voting securities of a Regulated Entity ("Shares"), then the Holders will vote such Shares as directed by an independent third party when voting on matters specified in the condition. Applicants believe that this condition will ensure that the Independent Trustees will act independently in evaluating the Co-Investment Program, because the ability of the Advisor or its principals to influence the Independent Trustees by a suggestion, explicit or implied, that the Independent Trustees can be removed will be limited significantly. Applicants represent that the Independent Trustees shall evaluate and approve any such independent third party, taking into account its qualifications, reputation for independence, cost to the shareholders, and other factors that they deem relevant.

Applicants' Legal Analysis

1. Section 17(d) of the Act and rule 17d–1 under the Act prohibit participation by a registered investment company and an affiliated person in any "joint enterprise or other joint arrangement or profit-sharing plan," as defined in the rule, without prior approval by the Commission by order upon application. Section 17(d) of the Act and rule 17d–1 under the Act are applicable to Regulated Entities that are registered closed-end investment companies. Similarly, with regard to BDCs, section 57(a)(4) of the Act makes it unlawful for any person who is related to a BDC in a manner described in section 57(b), acting as principal, knowingly to effect any transaction in which the BDC (or a company controlled by such BDC) is a joint or a joint and several participant with that person in contravention of rules as prescribed by the Commission. Because the Commission has not adopted any rules expressly under section 57(a)(4), section 57(i) provides that the rules under section 17(d) applicable to registered closed-end investment companies (*e.g.*, rule 17d–1) are, in the interim, deemed to apply to transactions subject to section 57(a). Rule 17d–1, as made applicable to BDCs by section 57(i), prohibits any person who is related to a BDC in a manner described in section 57(b), as modified by rule 57b–1, from acting as principal, from participating in, or effecting any transaction in connection with, any joint enterprise or other joint arrangement or profit-sharing plan in which the BDC (or a company controlled by such BDC) is a participant, unless an application regarding the joint enterprise, arrangement, or profit-sharing plan has been filed with the Commission and has been granted by an order entered prior to the submission of the plan or any modification thereof, to security holders for approval, or prior to its adoption or modification if not so submitted.

2. In passing upon applications under rule 17d–1, the Commission considers whether the company's participation in the joint transaction is consistent with the provisions, policies, and purposes of the Act and the extent to which such participation is on a basis different from or less advantageous than that of other participants.

3. Applicants submit that Each Regulated Entity may be deemed to be an "affiliated person" of each other Regulated Entity within the meaning of section 2(a)(3) of the Act. Applicants state that the Regulated Entities, by virtue of each having a Triloma Advisor, may be deemed to be under common control, and thus affiliated persons of each other under section 2(a)(3)(C) of the Act. Section 17(d) and section 57(b) apply to any investment adviser to a closed-end fund or a BDC, respectively, including the sub-adviser. Thus, an EIG Advisor and any Affiliated Investors that it advises could be deemed to be persons related to Regulated Entities in a manner described by sections 17(d) and 57(b) and therefore prohibited by sections 17(d) and 57(a)(4) and rule 17d–1 from participating in the Co-Investment Program. Applicants further submit that, because the EIG Advisors are "affiliated persons" of other EIG Advisors, Affiliated Investors advised by any of them could be deemed to be persons related to Regulated Entities (or a company controlled by a Regulated Entity) in a manner described by sections 17(d) and 57(b) and also prohibited from participating in the Co-Investment Program.

4. Applicants state that they expect that that co-investment in portfolio companies by a Regulated Entity, one or more other Regulated Entities and/or one or more Affiliated Investors will increase favorable investment opportunities for each Regulated Entity.

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[9] "Eligible Trustees" means the trustees or directors of a Regulated Entity that are eligible to vote under section 57(o) of the Act.

[10] In the case of a Regulated Entity that is a registered closed-end fund, the trustees or directors that make up the Required Majority will be determined as if the Regulated Entity were a BDC subject to section 57(o). As defined in section 57(o), "required majority" means "both a majority of a business development company's directors or general partners who have no financial interest in such transaction, plan, or arrangement and a majority of such directors or general partners who are not interested persons of such company."

5. Applicants submit that the fact that the Required Majority will approve each Co-Investment Transaction before investment (except for certain dispositions or follow-on investments, as described in the conditions), and other protective conditions set forth in the application, will ensure that each Regulated Entity will be treated fairly. Applicants state that each Regulated Entity's participation in the Co-Investment Transactions will be consistent with the provisions, policies and purposes of the Act and on a basis that is not different from or less advantageous than that of other participants. Applicants further state that the terms and conditions proposed herein will ensure that all such transactions are reasonable and fair to each Regulated Entity and the Affiliated Investors and do not involve overreaching by any person concerned, including Triloma or EIG.

Applicants' Conditions

Applicants agree that the Order will be subject to the following conditions:

1. Each time an EIG Advisor considers a Potential Co-Investment Transaction for an Affiliated Investor or another Regulated Entity that falls within a Regulated Entity's then-current Objectives and Strategies, the Advisors to the Regulated Entity will make an independent determination of the appropriateness of the investment for the Regulated Entity in light of the Regulated Entity's then-current circumstances.

2. a. If the Advisors to a Regulated Entity deem participation in any Potential Co-Investment Transaction to be appropriate for the Regulated Entity, the Advisors will then determine an appropriate level of investment for such Regulated Entity.

b. If the aggregate amount recommended by the Advisors to a Regulated Entity to be invested by the Regulated Entity in the Potential Co-Investment Transaction, together with the amount proposed to be invested by the other participating Regulated Entities and Affiliated Investors, collectively, in the same transaction, exceeds the amount of the investment opportunity, the amount of the investment opportunity will be allocated among the Regulated Entities and such Affiliated Investors, pro rata based on each participant's Available Capital[11] for investment in the asset class being allocated, up to the amount proposed to be invested by each. The Advisors to each participating Regulated Entity will provide the Eligible Trustees of each participating Regulated Entity with information concerning each participating party's Available Capital to assist the Eligible Trustees with their review of the Regulated Entity's investments for compliance with these allocation procedures.

c. After making the determinations required in conditions 1 and 2(a) above, the Advisors to the Regulated Entity will distribute written information concerning the Potential Co-Investment Transaction, including the amount proposed to be invested by each Regulated Entity and any Affiliated Investor, to the Eligible Trustees of each participating Regulated Entity for their consideration. A Regulated Entity will co-invest with one or more other Regulated Entities and/or an Affiliated Investor only if, prior to the Regulated Entities' and the Affiliated Investors' participation in the Potential Co-Investment Transaction, a Required Majority concludes that:

(i) The terms of the Potential Co-Investment Transaction, including the consideration to be paid, are reasonable and fair to the Regulated Entity and its shareholders and do not involve overreaching in respect of the Regulated Entity or its shareholders on the part of any person concerned;

(ii) the Potential Co-Investment Transaction is consistent with:

(a) The interests of the Regulated Entity's shareholders; and

(b) the Regulated Entity's then-current Objectives and Strategies;

(iii) the investment by any other Regulated Entity or an Affiliated Investor would not disadvantage the Regulated Entity, and participation by the Regulated Entity would not be on a basis different from or less advantageous than that of any other Regulated Entity or Affiliated Investor; provided, that if another Regulated Entity or Affiliated Investor, but not the Regulated Entity itself, gains the right to nominate a director for election to a portfolio company's board of directors or the right to have a board observer, or any similar right to participate in the governance or management of the portfolio company, such event shall not be interpreted to prohibit a Required Majority from reaching the conclusions required by this condition 2(c)(iii), if:

(a) The Eligible Trustees will have the right to ratify the selection of such director or board observer, if any; and

(b) the Advisors to the Regulated Entity agree to, and do, provide periodic reports to the Regulated Entity's Board with respect to the actions of such director or the information received by such board observer or obtained through the exercise of any similar right to participate in the governance or management of the portfolio company; and

(c) any fees or other compensation that any other Regulated Entity or any Affiliated Investor or any affiliated person of any other Regulated Entity or an Affiliated Investor receives in connection with the right of one or more Regulated Entities or Affiliated Investors to nominate a director or appoint a board observer or otherwise to participate in the governance or management of the portfolio company will be shared proportionately among the participating Affiliated Investors (who may, in turn, share their portion with their affiliated persons) and any participating Regulated Entity in accordance with the amount of each party's investment; and

(iv) the proposed investment by the Regulated Entity will not benefit the Advisors, any other Regulated Entity or the Affiliated Investors or any affiliated person of any of them (other than the parties to the Co-Investment Transaction), except (A) to the extent permitted by condition 13, (B) to the extent permitted under sections 17(e) and 57(k) of the Act, as applicable, (C) in the case of fees or other compensation described in condition 2(c)(iii)(c), or (D) indirectly, as a result of an interest in the securities issued by one of the parties to the Co-Investment Transaction.

3. Each Regulated Entity will have the right to decline to participate in any Potential Co-Investment Transaction or to invest less than the amount proposed.

4. The Advisors will present to the Board of each Regulated Entity, on a quarterly basis, a record of all investments in Potential Co-Investment Transactions made by any of the other Regulated Entities or any of the Affiliated Investors during the preceding quarter that fell within the Regulated Entity's then-current Objectives and Strategies that were not made available to the Regulated Entity, and an explanation of why the investment opportunities were not offered to the Regulated Entity. All

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[11] "Available Capital" means (a) for each Regulated Entity, the amount of capital available for investment determined based on the amount of cash on hand, existing commitments and reserves, if any, the targeted leverage level, targeted asset mix and other investment policies and restrictions set from time to time by the Board of the applicable Regulated Entity or imposed by applicable laws, rules, regulations or interpretations and (b) for each Affiliated Investor, the amount of capital available for investment determined based on the amount of cash on hand, existing commitments and reserves, if any, the targeted leverage level, targeted asset mix and other investment policies and restrictions set by the Affiliated Investor's directors, general partners or adviser or imposed by applicable laws, rules, regulations or interpretations.

information presented to the Board pursuant to this condition will be kept for the life of the Regulated Entity and at least two years thereafter, and will be subject to examination by the Commission and its staff.

5. Except for follow-on investments made in accordance with condition 8,[12] a Regulated Entity will not invest in reliance on the Order in any issuer in which another Regulated Entity or an Affiliated Investor or any affiliated person of another Regulated Entity or an Affiliated Investor is an existing investor.

6. A Regulated Entity will not participate in any Potential Co-Investment Transaction unless the terms, conditions, price, class of securities to be purchased, settlement date, and registration rights will be the same for each participating Regulated Entity and Affiliated Investor. The grant to one or more Regulated Entities or Affiliated Investors, but not the Regulated Entity itself, of the right to nominate a director for election to a portfolio company's board of directors, the right to have an observer on the board of directors or similar rights to participate in the governance or management of the portfolio company will not be interpreted so as to violate this condition 6, if conditions 2(c)(iii)(a), (b) and (c) are met.

7.a. If any Regulated Entity or Affiliated Investor elects to sell, exchange or otherwise dispose of an interest in a security that was acquired by one or more Regulated Entities and/or Affiliated Investors in a Co-Investment Transaction, the Advisors will:

(i) Notify each Regulated Entity that participated in the Co-Investment Transaction of the proposed disposition at the earliest practical time; and

(ii) formulate a recommendation as to participation by each Regulated Entity in the disposition.

b. Each Regulated Entity will have the right to participate in such disposition on a proportionate basis, at the same price and on the same terms and conditions as those applicable to the Affiliated Investors and any other Regulated Entity.

c. A Regulated Entity may participate in such disposition without obtaining prior approval of the Required Majority if: (i) The proposed participation of each Regulated Entity and each Affiliated Investor in such disposition is proportionate to its outstanding investments in the issuer immediately preceding the disposition; (ii) the Regulated Entity's Board has approved as being in the best interests of the Regulated Entity the ability to participate in such dispositions on a pro rata basis (as described in greater detail in the application); and (iii) the Regulated Entity's Board is provided on a quarterly basis with a list of all dispositions made in accordance with this condition. In all other cases, the Advisors will provide their written recommendation as to the Regulated Entity's participation to the Eligible Trustees, and the Regulated Entity will participate in such disposition solely to the extent that a Required Majority determines that it is in the Regulated Entity's best interests.

d. Each Regulated Entity and each Affiliated Investor will bear its own expenses in connection with the disposition.

8. a. If any Regulated Entity or Affiliated Investor desires to make a "follow-on investment" (*i.e.*, an additional investment in the same entity, including through the exercise of warrants or other rights to purchase securities of the issuer) in a portfolio company whose securities were acquired by the Regulated Entity and the Affiliated Investor in a Co-Investment Transaction, the Advisors will:

(i) Notify each Regulated Entity of the proposed transaction at the earliest practical time; and

(ii) formulate a recommendation as to the proposed participation, including the amount of the proposed follow-on investment, by each Regulated Entity.

b. A Regulated Entity may participate in such follow-on investment without obtaining prior approval of the Required Majority if: (i) The proposed participation of each Regulated Entity and each Affiliated Investor in such investment is proportionate to its outstanding investments in the issuer immediately preceding the follow-on investment; and (ii) the Regulated Entity's Board has approved as being in the best interests of such Regulated Entity the ability to participate in follow-on investments on a pro rata basis (as described in greater detail in the application). In all other cases, the Advisors will provide their written recommendation as to such Regulated Entity's participation to the Eligible Trustees, and the Regulated Entity will participate in such follow-on investment solely to the extent that the Required Majority determines that it is in such Regulated Entity's best interests.

c. If, with respect to any follow-on investment:

(i) The amount of a follow-on investment is not based on the Regulated Entities' and the Affiliated Investors' outstanding investments immediately preceding the follow-on investment; and

(ii) the aggregate amount recommended by the Advisors to be invested by the Regulated Entity in the follow-on investment, together with the amount proposed to be invested by the other participating Regulated Entities and the Affiliated Investors in the same transaction, exceeds the amount of the opportunity; then the amount invested by each such party will be allocated among them pro rata based on each participant's Available Capital for investment in the asset class being allocated, up to the amount proposed to be invested by each.

d. The acquisition of follow-on investments as permitted by this condition will be considered a Co-Investment Transaction for all purposes and be subject to the other conditions set forth in the application.

9. The Independent Trustees of each Regulated Entity will be provided quarterly for review all information concerning Potential Co-Investment Transactions and Co-Investment Transactions, including investments made by other Regulated Entities or Affiliated Investors that a Regulated Entity considered but declined to participate in, so that the Independent Trustees may determine whether all investments made during the preceding quarter, including those investments which the Regulated Entity considered but declined to participate in, comply with the conditions of the Order. In addition, the Independent Trustees will consider at least annually the continued appropriateness for such Regulated Entity of participating in new and existing Co-Investment Transactions.

10. Each Regulated Entity will maintain the records required by section 57(f)(3) of the Act as if each of the Regulated Entities were a BDC and each of the investments permitted under these conditions were approved by a Required Majority under section 57(f).

11. No Independent Trustee of a Regulated Entity will also be a trustee, director, general partner, managing member or principal, or otherwise an "affiliated person" (as defined in the Act) of any Affiliated Investor.

12. The expenses, if any, associated with acquiring, holding or disposing of any securities acquired in a Co-Investment Transaction (including, without limitation, the expenses of the distribution of any such securities registered for sale under the 1933 Act) shall, to the extent not payable by the

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[12] This exception applies only to follow-on investments by a Regulated Entity in issuers in which that Regulated Entity already holds investments.

Advisors under their respective advisory agreements with the Regulated Entities and the Affiliated Investors, be shared by the Regulated Entities and the Affiliated Investors in proportion to the relative amounts of the securities held or to be acquired or disposed of, as the case may be.

13. Any transaction fee (including break-up or commitment fees but excluding brokers' fees contemplated by section 17(e) or 57(k) of the Act, as applicable)[13] received in connection with a Co-Investment Transaction will be distributed to the participating Regulated Entities and Affiliated Investors on a pro rata basis based on the amount they invested or committed, as the case may be, in such Co-Investment Transaction. If any transaction fee is to be held by an Advisor pending consummation of the transaction, the fee will be deposited into an account maintained by the Advisor at a bank or banks having the qualifications prescribed in section 26(a)(1) of the Act, and the account will earn a competitive rate of interest that will also be divided pro rata among the participating Regulated Entities and Affiliated Investors based on the amount they invest in the Co-Investment Transaction. None of the other Regulated Entities, Affiliated Investors, the Advisors nor any affiliated person of the Regulated Entities or the Affiliated Investors will receive additional compensation or remuneration of any kind as a result of or in connection with a Co-Investment Transaction (other than (a) in the case of the Regulated Entities and the Affiliated Investors, the pro rata transaction fees described above and fees or other compensation described in condition 2(c)(iii)(c) and (b) in the case of the Advisors, investment advisory fees paid in accordance with the Regulated Entities' and the Affiliated Investors' investment advisory agreements).

14. The Advisors to the Regulated Entities and Affiliated Investors will maintain written policies and procedures reasonably designed to ensure compliance with the foregoing conditions. These policies and procedures will require, among other things, that each of the Advisors to each Regulated Entity will be notified of all Potential Co-Investment Transactions that fall within a Regulated Entity's then-current Objectives and Strategies and will be given sufficient information to make its independent determination and recommendations under conditions 1, 2(a), 7 and 8.

15. If the Holders own in the aggregate more than 25 percent of the shares of a Regulated Entity, then the Holders will vote such shares as directed by an independent third party when voting on (1) the election of directors or trustees; (2) the removal of one or more directors or trustees; or (3) any matters requiring approval by the vote of a majority of the outstanding voting securities, as defined in section 2(a)(42) of the Act.

For the Commission, by the Division of Investment Management, under delegated authority.

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–10960 Filed 5–9–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 32107; 812–14552]

Columbia ETF Trust I, et al.; Notice of Application

May 5, 2016.

AGENCY: Securities and Exchange Commission ("Commission").

ACTION: Notice.

SUMMARY: Notice of an application for an order under section 6(c) of the Investment Company Act of 1940 (the "Act") for an exemption from sections 2(a)(32), 5(a)(1), 22(d), and 22(e) of the Act and rule 22c–1 under the Act, under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and 17(a)(2) of the Act, and under section 12(d)(1)(J) for an exemption from sections 12(d)(1)(A) and 12(d)(1)(B) of the Act. The requested order would permit (a) index-based series of certain open-end management investment companies ("Funds") to issue shares redeemable in large aggregations only ("Creation Units"); (b) secondary market transactions in Fund shares to occur at negotiated market prices rather than at net asset value ("NAV"); (c) certain Funds to pay redemption proceeds, under certain circumstances, more than seven days after the tender of shares for redemption; (d) certain affiliated persons of a Fund to deposit securities into, and receive securities from, the Fund in connection with the purchase and redemption of Creation Units; (e) certain registered management investment companies and unit investment trusts outside of the same group of investment companies as the Funds ("Funds of Funds") to acquire shares of the Funds; and (f) certain Funds ("Feeder Funds") to create and redeem Creation Units in-kind in a master-feeder structure.

APPLICANTS: Columbia Management Investment Advisers, LLC (the "Initial Adviser"), a Minnesota limited liability company registered as an investment adviser under the Investment Advisers Act of 1940, Columbia ETF Trust I (the "Trust"), a Massachusetts business trust registered under the Act as an open-end management investment company with multiple series, and Columbia Management Investment Distributors, Inc. (the "Distributor"), a Delaware corporation and broker-dealer registered under the Securities Exchange Act of 1934 ("Exchange Act").

DATES: FILING DATES: The application was filed on September 28, 2015, and amended on January 19, 2016, April 15, 2016, April 27, 2016, and May 5, 2016.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on May 27, 2016, and should be accompanied by proof of service on applicants, in the form of an affidavit, or for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090; Applicants: Columbia ETF Trust I and Columbia Management Investment Distributors, Inc., 225 Franklin Street, Boston, Massachusetts 02110; Columbia Management Investment Advisers, LLC, 100 Park Avenue, 8th Floor, New York, New York 10017.

FOR FURTHER INFORMATION CONTACT: Jill Ehrlich, Senior Counsel at (202) 551–6819, or David J. Marcinkus, Branch Chief, at (202) 551–6821 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or for an applicant using the

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[13] Applicants are not requesting and the Commission is not providing any relief for transaction fees received in connection with any Co-Investment Transaction.

Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Summary of the Application

1. Applicants request an order that would allow Funds to operate as index exchange traded funds ("ETFs").[1] Fund shares will be purchased and redeemed at their NAV in Creation Units only. All orders to purchase Creation Units and all redemption requests will be placed by or through an "Authorized Participant", which will have signed a participant agreement with the Distributor. Shares will be listed and traded individually on a national securities exchange, where share prices will be based on the current bid/offer market. Certain Funds may operate as Feeder Funds in a master-feeder structure. Any order granting the requested relief would be subject to the terms and conditions stated in the application.

2. Each Fund will hold investment positions selected to correspond generally to the performance of an Underlying Index. In the case of Self-Indexing Funds, an affiliated person, as defined in section 2(a)(3) of the Act ("Affiliated Person"), or an affiliated person of an Affiliated Person ("Second-Tier Affiliate"), of the Trust or a Fund, of the Adviser, of any sub-adviser to or promoter of a Fund, or of the Distributor will compile, create, sponsor or maintain the Underlying Index.[2]

3. Shares will be purchased and redeemed in Creation Units and generally on an in-kind basis. Except where the purchase or redemption will include cash under the limited circumstances specified in the application, purchasers will be required to purchase Creation Units by depositing specified instruments ("Deposit Instruments"), and shareholders redeeming their shares will receive specified instruments ("Redemption Instruments"). The Deposit Instruments and the Redemption Instruments will each correspond pro rata to the positions in the Fund's portfolio (including cash positions) except as specified in the application.

4. Because shares will not be individually redeemable, applicants request an exemption from section 5(a)(1) and section 2(a)(32) of the Act that would permit the Funds to register as open-end management investment companies and issue shares that are redeemable in Creation Units only.

5. Applicants also request an exemption from section 22(d) of the Act and rule 22c-1 under the Act as secondary market trading in shares will take place at negotiated prices, not at a current offering price described in a Fund's prospectus, and not at a price based on NAV. Applicants state that (a) secondary market trading in shares does not involve a Fund as a party and will not result in dilution of an investment in shares, and (b) to the extent different prices exist during a given trading day, or from day to day, such variances occur as a result of third-party market forces, such as supply and demand. Therefore, applicants assert that secondary market transactions in shares will not lead to discrimination or preferential treatment among purchasers. Finally, applicants represent that share market prices will be disciplined by arbitrage opportunities, which should prevent shares from trading at a material discount or premium from NAV.

6. With respect to Funds that effect creations and redemptions of Creation Units in kind and that are based on certain Underlying Indexes that include foreign securities, applicants request relief from the requirement imposed by section 22(e) in order to allow such Funds to pay redemption proceeds within fourteen calendar days following the tender of Creation Units for redemption. Applicants assert that the requested relief would not be inconsistent with the spirit and intent of section 22(e) to prevent unreasonable, undisclosed or unforeseen delays in the actual payment of redemption proceeds.

7. Applicants request an exemption to permit Funds of Funds to acquire Fund shares beyond the limits of section 12(d)(1)(A) of the Act; and the Funds, and any principal underwriter for the Funds, and/or any broker or dealer registered under the Exchange Act, to sell shares to Funds of Funds beyond the limits of section 12(d)(1)(B) of the Act. The application's terms and conditions are designed to, among other things, help prevent any potential (i) undue influence over a Fund through control or voting power, or in connection with certain services, transactions, and underwritings, (ii) excessive layering of fees, and (iii) overly complex fund structures, which are the concerns underlying the limits in sections 12(d)(1)(A) and (B) of the Act.

8. Applicants request an exemption from sections 17(a)(1) and 17(a)(2) of the Act to permit persons that are Affiliated Persons, or Second Tier Affiliates, of the Funds, solely by virtue of certain ownership interests, to effectuate purchases and redemptions in-kind. The deposit procedures for in-kind purchases of Creation Units and the redemption procedures for in-kind redemptions of Creation Units will be the same for all purchases and redemptions and Deposit Instrument and Redemption Instruments will be valued in the same manner as those investment positions currently held by the Funds. Applicants also seek relief from the prohibitions on affiliated transactions in section 17(a) to permit a Fund to sell its shares to and redeem its shares from a Fund of Funds, and to engage in the accompanying in-kind transactions with the Fund of Funds.[3] The purchase of Creation Units by a Fund of Funds directly from a Fund will be accomplished in accordance with the policies of the Fund of Funds and will be based on the NAVs of the Funds.

9. Applicants also request relief to permit a Feeder Fund to acquire shares of another registered investment company managed by the Adviser having substantially the same investment objectives as the Feeder Fund ("Master Fund") beyond the limitations in section 12(d)(1)(A) and permit the Master Fund, and any principal underwriter for the Master Fund, to sell shares of the Master Fund to the Feeder Fund beyond the limitations in section 12(d)(1)(B).

10. Section 6(c) of the Act permits the Commission to exempt any persons or transactions from any provision of the Act if such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Section 12(d)(1)(J) of the Act provides that the Commission may exempt any person, security, or

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[1] Applicants request that the order apply to the initial funds and any additional series of the Trust, and any other open-end management investment company or series thereof, that may be created in the future (each, included in the term "Fund"), each of which will operate as an ETF and will track a specified index comprised of domestic or foreign equity and/or fixed income securities (each, an "Underlying Index"). Any Fund will (a) be advised by the Initial Adviser or an entity controlling, controlled by, or under common control with the Initial Adviser (each, an "Adviser") and (b) comply with the terms and conditions of the application.

[2] Each Self-Indexing Fund will post on its Web site the identities and quantities of the investment positions that will form the basis for the Fund's calculation of its NAV at the end of the day. Applicants believe that requiring Self-Indexing Funds to maintain full portfolio transparency will help address, together with other protections, conflicts of interest with respect to such Funds.

[3] The requested relief would apply to direct sales of shares in Creation Units by a Fund to a Fund of Funds and redemptions of those shares. Applicants, moreover, are not seeking relief from section 17(a) for, and the requested relief will not apply to, transactions where a Fund could be deemed an Affiliated Person, or a Second-Tier Affiliate, of a Fund of Funds because an Adviser or an entity controlling, controlled by or under common control with an Adviser provides investment advisory services to that Fund of Funds.

transaction, or any class or classes of persons, securities, or transactions, from any provision of section 12(d)(1) if the exemption is consistent with the public interest and the protection of investors. Section 17(b) of the Act authorizes the Commission to grant an order permitting a transaction otherwise prohibited by section 17(a) if it finds that (a) the terms of the proposed transaction are fair and reasonable and do not involve overreaching on the part of any person concerned; (b) the proposed transaction is consistent with the policies of each registered investment company involved; and (c) the proposed transaction is consistent with the general purposes of the Act.

For the Commission, by the Division of Investment Management, under delegated authority.

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–10984 Filed 5–9–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 32105; 812–14566]

Franklin Templeton ETF Trust, et al.; Notice of Application

May 5, 2016.

AGENCY: Securities and Exchange Commission ("Commission").

ACTION: Notice of an application for an order under section 6(c) of the Investment Company Act of 1940 (the "Act") for an exemption from sections 2(a)(32), 5(a)(1), 22(d), and 22(e) of the Act and rule 22c–1 under the Act, under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and 17(a)(2) of the Act, and under section 12(d)(1)(J) for an exemption from sections 12(d)(1)(A) and 12(d)(1)(B) of the Act. The requested order would permit (a) index-based series of certain open-end management investment companies ("Funds") to issue shares redeemable in large aggregations only ("Creation Units"); (b) secondary market transactions in Fund shares to occur at negotiated market prices rather than at net asset value ("NAV"); (c) certain Funds to pay redemption proceeds, under certain circumstances, more than seven days after the tender of shares for redemption; (d) certain affiliated persons of a Fund to deposit securities into, and receive securities from, the Fund in connection with the purchase and redemption of Creation Units; (e) certain registered management investment companies and unit investment trusts outside of the same group of investment companies as the Funds ("Funds of Funds") to acquire shares of the Funds; and (f) certain Funds ("Feeder Funds") to create and redeem Creation Units in-kind in a master-feeder structure.

Applicants: Franklin Templeton ETF Trust (the "Trust"), a Delaware statutory trust that will register under the Act as an open-end management investment company with multiple series, Franklin Advisers, Inc. (the "Initial Adviser), a California Corporation that is registered as an investment adviser under the Investment Advisers Act of 1940, and Franklin Templeton Distributors, Inc., a New York Corporation (together with any future distributor, the "Distributor").

DATES: *Filing Dates:* The application was filed on October 16, 2015, and amended on April 11, 2016.

Hearing or Notification of Hearing: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on May 27, 2016, and should be accompanied by proof of service on applicants, in the form of an affidavit, or for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090; Applicants: Franklin Templeton Investments, One Franklin Parkway, San Mateo, California 94403–1906.

FOR FURTHER INFORMATION CONTACT: Deepak T. Pai, Senior Counsel, at (202) 551–6876 or Mary Kay Frech, at (202) 551–6821 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Summary of the Application

1. Applicants request an order that would allow Funds to operate as index exchange traded funds ("ETFs").[1] Fund shares will be purchased and redeemed at their NAV in Creation Units only. All orders to purchase Creation Units and all redemption requests will be placed by or through an "Authorized Participant", which will have signed a participant agreement with the Distributor. Shares will be listed and traded individually on a national securities exchange, where share prices will be based on the current bid/offer market. Certain Funds may operate as Feeder Funds in a master-feeder structure. Any order granting the requested relief would be subject to the terms and conditions stated in the application.

2. Each Fund will hold investment positions selected to correspond generally to the performance of an Underlying Index. In the case of Self-Indexing Funds, an affiliated person, as defined in section 2(a)(3) of the Act ("Affiliated Person"), or an affiliated person of an Affiliated Person ("Second-Tier Affiliate"), of the Trust or a Fund, of the Adviser, of any sub-adviser to or promoter of a Fund, or of the Distributor will compile, create, sponsor or maintain the Underlying Index.[2]

3. Shares will be purchased and redeemed in Creation Units and generally on an in-kind basis. Except where the purchase or redemption will include cash under the limited circumstances specified in the application, purchasers will be required to purchase Creation Units by depositing specified instruments ("Deposit Instruments"), and shareholders redeeming their shares will receive specified instruments ("Redemption Instruments"). The Deposit Instruments and the Redemption Instruments will each correspond pro rata to the positions in the Fund's portfolio (including cash

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[1] Applicants request that the order apply to the initial series of the Trust and any additional series of the Trust, and any other existing or future open-end management investment company or series thereof (each, included in the term "Fund"), each of which will operate as an ETF and will track a specified index comprised of domestic or foreign equity and/or fixed income securities (each, an "Underlying Index"). Any Fund will (a) be advised by the Initial Adviser or an entity controlling, controlled by, or under common control with the Initial Adviser (each, an "Adviser") and (b) comply with the terms and conditions of the application.

[2] Each Self-Indexing Fund will post on its Web site the identities and quantities of the investment positions that will form the basis for the Fund's calculation of its NAV at the end of the day. Applicants believe that requiring Self-Indexing Funds to maintain full portfolio transparency will help address, together with other protections, conflicts of interest with respect to such Funds.

positions) except as specified in the application.

4. Because shares will not be individually redeemable, applicants request an exemption from section 5(a)(1) and section 2(a)(32) of the Act that would permit the Funds to register as open-end management investment companies and issue shares that are redeemable in Creation Units only.

5. Applicants also request an exemption from section 22(d) of the Act and rule 22c–1 under the Act as secondary market trading in shares will take place at negotiated prices, not at a current offering price described in a Fund's prospectus, and not at a price based on NAV. Applicants state that (a) secondary market trading in shares does not involve a Fund as a party and will not result in dilution of an investment in shares, and (b) to the extent different prices exist during a given trading day, or from day to day, such variances occur as a result of third-party market forces, such as supply and demand. Therefore, applicants assert that secondary market transactions in shares will not lead to discrimination or preferential treatment among purchasers. Finally, applicants represent that share market prices will be disciplined by arbitrage opportunities, which should prevent shares from trading at a material discount or premium from NAV.

6. With respect to Funds that effect creations and redemptions of Creation Units in kind and that are based on certain Underlying Indexes that include foreign securities, applicants request relief from the requirement imposed by section 22(e) in order to allow such Funds to pay redemption proceeds within fifteen calendar days following the tender of Creation Units for redemption. Applicants assert that the requested relief would not be inconsistent with the spirit and intent of section 22(e) to prevent unreasonable, undisclosed or unforeseen delays in the actual payment of redemption proceeds.

7. Applicants request an exemption to permit Funds of Funds to acquire Fund shares beyond the limits of section 12(d)(1)(A) of the Act; and the Funds, and any principal underwriter for the Funds, and/or any broker or dealer registered under the Securities Exchange Act of 1934, to sell shares to Funds of Funds beyond the limits of section 12(d)(1)(B) of the Act. The application's terms and conditions are designed to, among other things, help prevent any potential (i) undue influence over a Fund through control or voting power, or in connection with certain services, transactions, and underwritings, (ii) excessive layering of fees, and (iii) overly complex fund structures, which are the concerns underlying the limits in sections 12(d)(1)(A) and (B) of the Act.

8. Applicants request an exemption from sections 17(a)(1) and 17(a)(2) of the Act to permit persons that are Affiliated Persons, or Second Tier Affiliates, of the Funds, solely by virtue of certain ownership interests, to effectuate purchases and redemptions in-kind. The deposit procedures for in-kind purchases of Creation Units and the redemption procedures for in-kind redemptions of Creation Units will be the same for all purchases and redemptions and Deposit Instruments and Redemption Instruments will be valued in the same manner as those investment positions currently held by the Funds. Applicants also seek relief from the prohibitions on affiliated transactions in section 17(a) to permit a Fund to sell its shares to and redeem its shares from a Fund of Funds, and to engage in the accompanying in-kind transactions with the Fund of Funds.[3] The purchase of Creation Units by a Fund of Funds directly from a Fund will be accomplished in accordance with the policies of the Fund of Funds and will be based on the NAVs of the Funds.

9. Applicants also request relief to permit a Feeder Fund to acquire shares of another registered investment company managed by the Adviser having substantially the same investment objectives as the Feeder Fund ("Master Fund") beyond the limitations in section 12(d)(1)(A) and permit the Master Fund, and any principal underwriter for the Master Fund, to sell shares of the Master Fund to the Feeder Fund beyond the limitations in section 12(d)(1)(B).

10. Section 6(c) of the Act permits the Commission to exempt any persons or transactions from any provision of the Act if such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Section 12(d)(1)(J) of the Act provides that the Commission may exempt any person, security, or transaction, or any class or classes of persons, securities, or transactions, from any provision of section 12(d)(1) if the exemption is consistent with the public interest and the protection of investors. Section 17(b) of the Act authorizes the Commission to grant an order permitting a transaction otherwise prohibited by section 17(a) if it finds that (a) the terms of the proposed transaction are fair and reasonable and do not involve overreaching on the part of any person concerned; (b) the proposed transaction is consistent with the policies of each registered investment company involved; and (c) the proposed transaction is consistent with the general purposes of the Act.

For the Commission, by the Division of Investment Management, under delegated authority.

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–10983 Filed 5–9–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 32103; File No. 812–14492]

Bridge Builder Trust and Olive Street Investment Advisers, LLC; Notice of Application

May 4, 2016

AGENCY: Securities and Exchange Commission ("Commission").

ACTION: Notice of an application for an order pursuant to: (a) section 6(c) of the Investment Company Act of 1940 ("Act") granting an exemption from sections 18(f) and 21(b) of the Act; (b) section 12(d)(1)(J) of the Act granting an exemption from section 12(d)(1) of the Act; (c) sections 6(c) and 17(b) of the Act granting an exemption from sections 17(a)(1), 17(a)(2) and 17(a)(3) of the Act; and (d) section 17(d) of the Act and rule 17d-1 under the Act to permit certain joint arrangements and transactions.

SUMMARY OF THE APPLICATION: Applicants request an order that would permit certain registered open-end management investment companies to participate in a joint lending and borrowing facility.

APPLICANTS: Bridge Builder Trust (the "Trust") and Olive Street Investment Advisers, LLC ("Olive Street" or the "Adviser").

FILING DATES: The application was filed on June 18, 2015, and amended on December 2, 2015, March 9, 2016, and May 4, 2016.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the

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[3] The requested relief would apply to direct sales of shares in Creation Units by a Fund to a Fund of Funds and redemptions of those shares. Applicants, moreover, are not seeking relief from section 17(a) for, and the requested relief will not apply to, transactions where a Fund could be deemed an Affiliated Person, or a Second-Tier Affiliate, of a Fund of Funds because an Adviser or an entity controlling, controlled by or under common control with an Adviser provides investment advisory services to that Fund of Funds.

Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on May 31, 2016, and should be accompanied by proof of service on the applicants, in the form of an affidavit, or, for lawyers, a certificate of service. Pursuant to Rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090; Applicants: Joseph C. Neuberger, President and Elaine Richards, Secretary, Bridge Builder Trust, 2020 East Financial Way Suite 100, Glendora, CA 91741, Sean Graber, Esq. Morgan, Lewis & Bockius LLP, 1701 Market Street, Philadelphia, PA 19103, and Helge K. Lee, Esq., Edward D. Jones & Co. L.P., 12555 Manchester Road, St. Louis MO 63131.

FOR FURTHER INFORMATION CONTACT: Laura L. Solomon, Senior Counsel, at (202) 551–6915 or Daniele Marchesani, Branch Chief, at (202) 551–6821 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Applicants' Representations

1. The Trust is organized as a Delaware statutory trust and is registered under the Act as an open-end management investment company. The Trust has issued one or more series, each of which has shares having a different investment objective and different investment policies. Certain of the Funds[1] either are or may be money market funds that comply with rule 2a-7 under the Act (each a "Money Market Fund" and collectively, the "Money Market Funds"). Olive Street is a Missouri limited liability company that is registered as an investment adviser under the Investment Advisers Act of 1940 ("Advisers Act"). Olive Street is a wholly-owned subsidiary of The Jones Financial Companies, L.L.L.P. ("JFC") and is affiliated with other subsidiaries of JFC, including Edward D. Jones & Co., L.P., and Edward Jones Trust Company. Currently, Olive Street acts as investment adviser only to the Trust.[2]

2. The Funds may lend cash to banks or other entities by entering into repurchase agreements or purchasing other short-term instruments. In order to meet an unexpected volume of redemptions or to cover unanticipated cash shortfalls, the Funds contracted for a revolving credit facility with U.S. Bank National Association ("U.S. Bank"), the Funds' custodian ("Bank Borrowing").

3. If Funds that experience a cash shortfall were to use Bank Borrowing, they would pay interest at a rate that is likely to be higher than the rate that could be earned by non-borrowing Funds on investments in repurchase agreements and other short-term money market instruments of the same maturity as the Bank Borrowing ("Short-Term Instruments"). Applicants assert this differential represents the bank's profit for serving as the middleperson between a borrower and lender and is not attributable to any material difference in the credit quality or risk of such transactions.

4. The Funds seek to enter into a master interfund lending agreement with each other that would permit each Fund to lend money directly to and borrow money directly from other Funds for temporary purposes through the InterFund Program (an "Interfund Loan"). The Money Market Funds typically will not participate as borrowers. Applicants state that the requested relief will enable the Funds to access an available source of money and reduce costs incurred by the Funds that need to obtain loans for temporary purposes and permit those Funds that have uninvested cash available: (i) to earn a return on the money that they might not otherwise be able to invest; or (ii) to earn a higher rate of interest on investment of their short-term balances. Although the proposed InterFund Program would reduce the Funds' need to borrow from banks or through custodian overdrafts, the Funds would be free to establish and/or continue committed lines of credit or other borrowing arrangements with banks.

5. Applicants anticipate that the proposed InterFund Program would provide a borrowing Fund with significant savings at times when the cash position of the Fund is insufficient to meet temporary cash requirements. This situation could arise when shareholder redemptions exceed anticipated cash volumes and certain Funds have insufficient cash on hand to satisfy such redemptions. When the Funds liquidate portfolio securities to meet redemption requests, they often do not receive payment in settlement for up to three days (or longer for certain foreign transactions). However, redemption requests normally are effected on the day following the trade date. The proposed InterFund Program would provide a source of immediate, short-term liquidity pending settlement of the sale of portfolio securities.

6. Applicants also anticipate that a Fund could use the InterFund Program when a sale of securities "fails" due to circumstances beyond the Fund's control, such as a delay in the delivery of cash to the Fund's custodian or improper delivery instructions by the broker effecting the transaction. "Sales fails" may present a cash shortfall if the Fund has undertaken to purchase a security using the proceeds from securities sold. Alternatively, the Fund could: (i) "fail" on its intended purchase due to lack of funds from the previous sale, resulting in additional cost to the Fund; or (ii) sell a security on a same-day settlement basis, earning a lower return on the investment. Use of the InterFund Program under these circumstances would enable the Fund to have access to immediate short-term liquidity.

7. While Bank Borrowing and/or custodian overdrafts generally could supply Funds with needed cash to cover unanticipated redemptions and sales fails, under the proposed InterFund Program, a borrowing Fund would pay lower interest rates than those that would be payable under short-term loans offered by banks or custodian overdrafts. In addition, Funds making short-term cash loans directly to other Funds would earn interest at a rate higher than they otherwise could obtain from investing their cash in Short-Term Instruments. Thus, applicants assert that the proposed InterFund Program would benefit both borrowing and lending Funds.

8. The interest rate to be charged to the Funds on any Interfund Loan (the

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[1] Applicants request that the order apply to any registered open-end management investment company or series thereof for which Olive Street or any successor thereto or an investment adviser controlling, controlled by, or under common control (within the meaning of section 2(a)(9) of the Act) with Olive Street or any successor thereto serves as investment adviser (each a "Fund" and collectively the "Funds" and each such investment adviser as "Adviser"). For purposes of the requested order, "successor" is limited to any entity that results from a reorganization into another jurisdiction or a change in the type of a business organization.

[2] All Funds that currently intend to rely on the requested order have been named as applicants. Any other Fund that relies on the requested order in the future will comply with the terms and conditions of the application.

"Interfund Loan Rate") would be the average of the "Repo Rate" and the "Bank Loan Rate," both as defined below. The Repo Rate would be the highest current overnight repurchase agreement rate available to a lending Fund. The Bank Loan Rate for any day would be calculated by the InterFund Program Team, as defined below, on each day an Interfund Loan is made according to a formula established by each Fund's board of trustees (the "Board") intended to approximate the lowest interest rate at which a bank short-term loan would be available to the Fund. The formula would be based upon a publicly available rate (*e.g.,* Federal funds rate and/or LIBOR) plus an additional spread of basis points and would vary with this rate so as to reflect changing bank loan rates. The initial formula and any subsequent modifications to the formula would be subject to the approval of each Fund's Board. In addition, the Board of each Fund would periodically review the continuing appropriateness of reliance on the formula used to determine the Bank Loan Rate, as well as the relationship between the Bank Loan Rate and current bank loan rates that would be available to the Fund.

9. Investment professionals and administrative personnel from the Adviser and its affiliates (the "InterFund Program Team") would administer the InterFund Program. No portfolio manager of any Fund will serve as a member of the InterFund Program Team. Under the proposed InterFund Program, the portfolio managers for each participating Fund could provide standing instructions to participate daily as a borrower or lender. The InterFund Program Team on each business day would collect data on the uninvested cash and borrowing requirements of all participating Funds. Once the InterFund Program Team has determined the aggregate amount of cash available for loans and borrowing demand, the InterFund Program Team would allocate loans among borrowing Funds without any further communication from the portfolio managers of the Funds. Applicants anticipate that there typically will be far more available uninvested cash each day than borrowing demand. Therefore, after the InterFund Program Team has allocated cash for Interfund Loans, the InterFund Program Team will invest any remaining cash in accordance with the standing instructions of the relevant portfolio manager or such remaining amounts will be invested directly by the portfolio managers of the Funds.

10. The InterFund Program Team would allocate borrowing demand and cash available for lending among the Funds on what the InterFund Program Team believes to be an equitable basis, subject to certain administrative procedures applicable to all Funds, such as the time of filing requests to participate, minimum loan lot sizes, and the need to minimize the number of transactions and associated administrative costs. To reduce transaction costs, each Interfund Loan normally would be allocated in a manner intended to minimize the number of participants necessary to complete the loan transaction. The method of allocation and related administrative procedures would be approved by each Fund's Board, including a majority of the Board members who are not "interested persons," as defined in section 2(a)(19) of the Act, of the Fund ("Independent Board Members"), to ensure that both borrowing and lending Funds participate on an equitable basis.

11. As part of the Board's review of the continuing appropriateness of a Fund's participation in the InterFund Program, as required below by condition 14, the Board, including a majority of the Independent Board Members, also will review the process in place to appropriately assess: (a) If the Fund participates as a lender, any effect its participation may have on the Fund's liquidity risk; and (b) if the Fund participates as a borrower, whether the Fund's portfolio liquidity is sufficient to satisfy its obligations under the InterFund Program along with its other liquidity needs.

12. The InterFund Program Team would: (a) Monitor the Interfund Loan Rate and the other terms and conditions of the Interfund Loans; (b) limit the borrowings and loans entered into by each Fund to ensure that they comply with the Fund's investment policies and limitations; (c) ensure equitable treatment of each Fund; and (d) make quarterly reports to the Board concerning any transactions by the Funds under the InterFund Program and the Interfund Loan Rate charged.

13. The Adviser, through the InterFund Program Team, would administer the InterFund Program as a disinterested fiduciary as part of its duties under the investment management agreement with each Fund and would receive no additional fee as compensation for its services in connection with the administration of the InterFund Program.

14. No Fund may participate in the InterFund Program unless: (a) The Fund has obtained shareholder approval for its participation, if such approval is required by law; (b) the Fund has fully disclosed all material information concerning the InterFund Program in its registration statement on form N–1A; and (c) the Fund's participation in the InterFund Program is consistent with its investment objectives, limitations and organizational documents.

15. In connection with the InterFund Program, applicants request an order under section 6(c) of the Act exempting them from the provisions of sections 18(f) and 21(b) of the Act; under section 12(d)(1)(J) of the Act exempting them from section 12(d)(1) of the Act; under sections 6(c) and 17(b) of the Act exempting them from sections 17(a)(1), 17(a)(2), and 17(a)(3) of the Act; and under section 17(d) of the Act and rule 17d–1 under the Act to permit certain joint arrangements and transactions.

Applicants' Legal Analysis

1. Section 17(a)(3) of the Act generally prohibits any affiliated person of a registered investment company, or affiliated person of an affiliated person, from borrowing money or other property from the registered investment company. Section 21(b) of the Act generally prohibits any registered management company from lending money or other property to any person, directly or indirectly, if that person controls or is under common control with that company. Section 2(a)(3)(C) of the Act defines an "affiliated person" of another person, in part, to be any person directly or indirectly controlling, controlled by, or under common control with, such other person. Section 2(a)(9) of the Act defines "control" as the "power to exercise a controlling influence over the management or policies of a company," but excludes circumstances in which "such power is solely the result of an official position with such company." Applicants state that the Funds may be under common control by virtue of having a common investment adviser and/or by having common trustees and officers.

2. Section 6(c) of the Act provides that an exemptive order may be granted where an exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Section 17(b) of the Act authorizes the Commission to exempt a proposed transaction from section 17(a) provided that the terms of the transaction, including the consideration to be paid or received, are fair and reasonable and do not involve overreaching on the part of any person concerned, and the transaction is consistent with the policy of the investment company as recited in its

registration statement and with the general purposes of the Act. Applicants believe that the proposed arrangements satisfy these standards for the reasons discussed below.

3. Applicants assert that sections 17(a)(3) and 21(b) of the Act were intended to prevent a party with strong potential adverse interests to, and some influence over the investment decisions of, a registered investment company from causing or inducing the investment company to engage in lending transactions that unfairly inure to the benefit of such party and that are detrimental to the best interests of the investment company and its shareholders. Applicants assert that the proposed transactions do not raise these concerns because: (a) The Adviser, through the InterFund Program Team, would administer the InterFund Program as a disinterested fiduciary as part of its duties under the investment management agreement with each Fund; (b) all Interfund Loans would consist only of uninvested cash reserves that the Fund otherwise would invest in Short-Term Instruments; (c) the Interfund Loans would not involve a greater risk than such other investments; (d) the lending Fund would receive interest at a rate higher than it could otherwise obtain through such other investments; and (e) the borrowing Fund would pay interest at a rate lower than otherwise available to it under its bank loan agreements or through custodian overdrafts and avoid the commitment fees associated with lines of credit. Moreover, applicants assert that the other terms and conditions that applicants propose also would effectively preclude the possibility of any Fund obtaining an undue advantage over any other Fund.

4. Section 17(a)(1) of the Act generally prohibits an affiliated person of a registered investment company, or any affiliated person of such a person, from selling securities or other property to the investment company. Section 17(a)(2) of the Act generally prohibits an affiliated person of a registered investment company, or any affiliated person of such a person, from purchasing securities or other property from the investment company. Section 12(d)(1) of the Act generally prohibits a registered investment company from purchasing or otherwise acquiring any security issued by any other investment company except in accordance with the limitations set forth in that section.

5. Applicants state that the obligation of a borrowing Fund to repay an Interfund Loan could be deemed to constitute a security for the purposes of sections 17(a)(1) and 12(d)(1). Applicants also state that any pledge of securities to secure an Interfund Loan by the borrowing Fund to the lending Fund could constitute a purchase of securities for purposes of section 17(a)(2) of the Act. Section 12(d)(1)(J) of the Act provides that the Commission may exempt persons or transactions from any provision of section 12(d)(1) if and to the extent that such exemption is consistent with the public interest and the protection of investors. Applicants contend that the standards under sections 6(c), 17(b), and 12(d)(1)(J) are satisfied for all the reasons set forth above in support of their request for relief from sections 17(a)(3) and 21(b) and for the reasons discussed below. Applicants state that the requested relief from section 17(a)(2) of the Act meets the standards of section 6(c) and 17(b) because any collateral pledged to secure an Interfund Loan would be subject to the same conditions imposed by any other lender to a Fund that imposes conditions on the quality of or access to collateral for a borrowing (if the lender is another Fund) or the same or better conditions (in any other circumstance).

6. Applicants state that section 12(d)(1) was intended to prevent the pyramiding of investment companies in order to avoid imposing on investors additional and duplicative costs and fees attendant upon multiple layers of investment companies. Applicants submit that the proposed InterFund Program does not involve these abuses. Applicants note that there will be no duplicative costs or fees to the Funds or their shareholders, and that each Adviser will receive no additional compensation for its services in administering the InterFund Program. Applicants also note that the purpose of the proposed InterFund Program is to provide economic benefits for all the participating Funds and their shareholders. Section 18(f)(1) of the Act prohibits open-end investment companies from issuing any senior security except that a company is permitted to borrow from any bank, provided, that immediately after the borrowing, there is asset coverage of at least 300 per centum for all borrowings of the company. Under section 18(g) of the Act, the term "senior security" generally includes any bond, debenture, note or similar obligation or instrument constituting a security and evidencing indebtedness. Applicants request exemptive relief under section 6(c) from section 18(f)(1) to the limited extent necessary to implement the InterFund Program (because the lending Funds are not banks).

7. Applicants believe that granting relief under section 6(c) is appropriate because the Funds would remain subject to the requirement of section 18(f)(1) that all borrowings of a Fund, including combined Interfund Loans and bank borrowings, have at least 300% asset coverage. Based on the conditions and safeguards described in the application, applicants also submit that to allow the Funds to borrow from other Funds pursuant to the proposed InterFund Program is consistent with the purposes and policies of section 18(f)(1).

8. Section 17(d) of the Act and rule 17d–1 under the Act generally prohibit an affiliated person of a registered investment company, or any affiliated person of such a person, when acting as principal, from effecting any joint transaction in which the investment company participates, unless, upon application, the transaction has been approved by the Commission. Rule 17d–1(b) under the Act provides that in passing upon an application filed under the rule, the Commission will consider whether the participation of the registered investment company in a joint enterprise, joint arrangement or profit sharing plan on the basis proposed is consistent with the provisions, policies and purposes of the Act and the extent to which such participation is on a basis different from or less advantageous than that of the other participants.

9. Applicants assert that the purpose of section 17(d) is to avoid overreaching by and unfair advantage to insiders. Applicants assert that the InterFund Program is consistent with the provisions, policies and purposes of the Act in that it offers both reduced borrowing costs and enhanced returns on loaned funds to all participating Funds and their shareholders. Applicants note that each Fund would have an equal opportunity to borrow and lend on equal terms consistent with its investment policies and limitations. Applicants assert that each Fund's participation in the proposed InterFund Program would be on terms that are no different from or less advantageous than that of other participating Funds.

Applicants' Conditions

Applicants agree that any order granting the requested relief will be subject to the following conditions:

1. The Interfund Loan Rate will be the average of the Repo Rate and the Bank Loan Rate.

2. On each business day when an Interfund Loan is to be made, the InterFund Program Team will compare the Bank Loan Rate with the Repo Rate

and will make cash available for Interfund Loans only if the Interfund Loan Rate is: (a) More favorable to the lending Fund than the Repo Rate; and (b) more favorable to the borrowing Fund than the Bank Loan Rate.

3. If a Fund has outstanding Bank Borrowings, any Interfund Loan to the Fund will: (a) Be at an interest rate equal to or lower than the interest rate of any outstanding bank loan; (b) be secured at least on an equal priority basis with at least an equivalent percentage of collateral to loan value as any outstanding bank loan that requires collateral; (c) have a maturity no longer than any outstanding bank loan (and in any event not over seven days); and (d) provide that, if an event of default by the Fund occurs under any agreement evidencing an outstanding bank loan to the Fund, that event of default will automatically (without need for action or notice by the lending Fund) constitute an immediate event of default under the interfund lending agreement, which both (i) entitles the lending Fund to call the Interfund Loan immediately and exercise all rights with respect to any collateral and (ii) causes the call to be made if the lending bank exercises its right to call its loan under its agreement with the borrowing Fund.

4. A Fund may borrow on an unsecured basis through the InterFund Program only if its outstanding borrowings from all sources immediately after the interfund borrowing total 10% or less of its total assets, provided that if the Fund has a secured loan outstanding from any other lender, including but not limited to another Fund, the Interfund Loan will be secured on at least an equal priority basis with at least an equivalent percentage of collateral to loan value as any outstanding loan that requires collateral. If a Fund's total outstanding borrowings immediately after an Interfund Loan would be greater than 10% of its total assets, the Fund may borrow through the InterFund Program only on a secured basis. A Fund may not borrow through the InterFund Program or from any other source if its total outstanding borrowings immediately after the borrowing would be more than 33⅓% of its total assets or any lower threshold provided for by a Fund's fundamental restriction or non-fundamental policy.

5. Before any Fund that has outstanding interfund borrowings may, through additional borrowings, cause its outstanding borrowings from all sources to exceed 10% of its total assets, it must first secure each outstanding Interfund Loan by the pledge of segregated collateral with a market value at least equal to 102% of the outstanding principal value of the loan. If the total outstanding borrowings of a Fund with outstanding Interfund Loans exceed 10% of its total assets for any other reason (such as a decline in net asset value or because of shareholder redemptions), the Fund will within one business day thereafter either: (a) Repay all its outstanding Interfund Loans; (b) reduce its outstanding indebtedness to 10% or less of its total assets; or (c) secure each outstanding Interfund Loan by the pledge of segregated collateral with a market value at least equal to 102% of the outstanding principal value of the loan until the Fund's total outstanding borrowings cease to exceed 10% of its total assets, at which time the collateral called for by this condition 5 shall no longer be required. Until each Interfund Loan that is outstanding at any time that a Fund's total outstanding borrowings exceed 10% of its total assets is repaid or the Fund's total outstanding borrowings cease to exceed 10% of its total assets, the Fund will mark the value of the collateral to market each day and will pledge such additional collateral as is necessary to maintain the market value of the collateral that secures each outstanding Interfund Loan at least equal to 102% of the outstanding principal value of the Interfund Loan.

6. No Fund may lend to another Fund through the InterFund Program if the loan would cause the lending Fund's aggregate outstanding loans through the InterFund Program to exceed 15% of its current net assets at the time of the loan.

7. A Fund's Interfund Loans to any one Fund shall not exceed 5% of the lending Fund's net assets.

8. The duration of Interfund Loans will be limited to the time required to receive payment for securities sold, but in no event more than seven days. Loans effected within seven days of each other will be treated as separate loan transactions for purposes of this condition.

9. A Fund's borrowings through the InterFund Program, as measured on the day when the most recent loan was made, will not exceed the greater of 125% of the Fund's total net cash redemptions for the preceding seven calendar days or 102% of the Fund's sales fails for the preceding seven calendar days.

10. Each Interfund Loan may be called on one business day's notice by a lending Fund and may be repaid on any day by a borrowing Fund.

11. A Fund's participation in the InterFund Program must be consistent with its investment objectives and limitations and organizational documents.

12. The InterFund Program Team will calculate total Fund borrowing and lending demand through the InterFund Program, and allocate Interfund Loans on an equitable basis among the Funds, without the intervention of any portfolio manager. The InterFund Program Team will not solicit cash for the InterFund Program from any Fund or prospectively publish or disseminate loan demand data to portfolio managers. The InterFund Program Team will invest all amounts remaining after satisfaction of borrowing demand in accordance with the standing instructions of the relevant portfolio manager or such remaining amounts will be invested directly by the portfolio managers of the Funds.

13. The InterFund Program Team will monitor the Interfund Loan Rate charged and the other terms and conditions of the Interfund Loans and will make a quarterly report to the Board concerning the participation of the Funds in the InterFund Program and the terms and other conditions of any extensions of credit under the InterFund Program.

14. Each Board, including a majority of the Independent Board Members, will:

(a) Review, no less frequently than quarterly, the participation of each Fund it oversees in the InterFund Program during the preceding quarter for compliance with the conditions of any order permitting such participation;

(b) establish the Bank Loan Rate formula used to determine the interest rate on Interfund Loans;

(c) review, no less frequently than annually, the continuing appropriateness of the Bank Loan Rate formula; and

(d) review, no less frequently than annually, the continuing appropriateness of the participation in the InterFund Program by each Fund it oversees.

15. Each Fund will maintain and preserve for a period of not less than six years from the end of the fiscal year in which any transaction by it under the InterFund Program occurred, the first two years in an easily accessible place, written records of all such transactions setting forth a description of the terms of the transaction, including the amount, the maturity and the Interfund Loan Rate, the rate of interest available at the time each Interfund Loan is made on overnight repurchase agreements and Bank Borrowings, and such other information presented to the Board in connection with the review required by conditions 13 and 14.

16. In the event an Interfund Loan is not paid according to its terms and the default is not cured within two business days from its maturity or from the time the lending Fund makes a demand for payment under the provisions of the interfund lending agreement, the InterFund Program Team will promptly refer the loan for arbitration to an independent arbitrator selected by the Board of each Fund involved in the loan who will serve as arbitrator of disputes concerning Interfund Loans.[3] The arbitrator will resolve any dispute promptly, and the arbitrator's decision will be binding on both Funds. The arbitrator will submit, at least annually, a written report to the Board setting forth a description of the nature of any dispute and the actions taken by the Funds to resolve the dispute.

17. The InterFund Program Team will prepare and submit to the Board for review an initial report describing the operations of the InterFund Program and the procedures to be implemented to ensure that all Funds are treated fairly. After the commencement of the InterFund Program, the InterFund Program Team will report on the operations of the InterFund Program at the Board's quarterly meetings. Each Fund's chief compliance officer, as defined in rule 38a–1(a)(4) under the Act, shall prepare an annual report for the Board each year that the Fund participates in the InterFund Program, that evaluates the Fund's compliance with the terms and conditions of the application and the procedures established to achieve such compliance. Each Fund's chief compliance officer will also annually file a certification pursuant to Item 77Q3 of Form N–SAR as such Form may be revised, amended or superseded from time to time, for each year that the Fund participates in the InterFund Program, that certifies that the Fund and the Adviser have implemented procedures reasonably designed to achieve compliance with the terms and conditions of the order. In particular, such certification will address procedures designed to achieve the following objectives:

(a) That the Interfund Loan Rate will be higher than the Repo Rate but lower than the Bank Loan Rate;

(b) compliance with the collateral requirements as set forth in the application;

(c) compliance with the percentage limitations on interfund borrowing and lending;

(d) allocation of interfund borrowing and lending demand in an equitable manner and in accordance with procedures established by the Board; and

(e) that the Interfund Loan Rate does not exceed the interest rate on any third party borrowings of a borrowing Fund at the time of the Interfund Loan.

Additionally, each Fund's independent registered public accountants, in connection with their audit examination of the Fund, will review the operation of the InterFund Program for compliance with the conditions of the application and their review will form the basis, in part, of the auditor's report on internal accounting controls in Form N–SAR.

18. No Fund will participate in the InterFund Program, upon receipt of requisite regulatory approval, unless it has fully disclosed in its registration statement on Form N–1A (or any successor form adopted by the Commission) all material facts about its intended participation.

For the Commission, by the Division of Investment Management, under delegated authority.

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–10917 Filed 5–9–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–389, OMB Control No. 3235–0444]

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE., Washington, DC 20549–2736.

Extension:
Rule 10b–10.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) ("PRA"), the Securities and Exchange Commission ("Commission") has submitted to the Office of Management and Budget ("OMB") a request for approval of extension of the previously approved collection of information provided for in Rule 10b–10 (17 CFR 240.10b–10) under the Securities and Exchange Act of 1934 (15 U.S.C. 78a *et seq.*).

Rule 10b–10 requires broker-dealers to convey specified information to customers regarding their securities transactions. This information includes the date and time of the transaction, the identity and number of shares bought or sold, and whether the broker-dealer acts as agent for the customer or as principal for its own account. Depending on whether the broker-dealer acts as agent or principal, Rule 10b–10 requires the disclosure of commissions, as well as mark-up and mark-down information. For transactions in debt securities, Rule 10b–10 requires the disclosure of redemption and yield information. Rule 10b–10 potentially applies to all of the approximately 4,183 firms registered with the Commission that effect transactions for or with customers.

Based on information provided by registered broker-dealers to the Commission in FOCUS Reports, the Commission staff estimates that on average, registered broker-dealers process approximately 1,383,492,184 order tickets per month for transactions for or with customers. Each order ticket representing a transaction effected for or with a customer results in one confirmation. Therefore, the Commission staff estimates that approximately 16,601,906,208 confirmations are sent to customers annually. The confirmations required by Rule 10b–10 are generally processed through automated systems. It takes approximately 30 seconds to generate and send a confirmation. Accordingly, the Commission staff estimates that broker-dealers spend approximately 138,349,218 hours per year complying with Rule 10b–10.

The amount of confirmations sent and the cost of sending each confirmation varies from firm to firm. Smaller firms generally send fewer confirmations than larger firms because they effect fewer transactions. The Commission staff estimates the costs of producing and sending a paper confirmation, including postage, to be approximately 57 cents. The Commission staff also estimates that the cost of producing and sending a wholly electronic confirmation is approximately 39 cents. Based on informal discussions with industry participants, as well as representations made in requests for exemptive and no-action letters relating to Rule 10b–10, the staff estimates that broker-dealers used electronic confirmations for approximately 35 percent of transactions. Based on these calculations, Commission staff estimates that 10,791,239, 035 paper confirmations are mailed each year at a cost of $6,151,006,250. Commission staff also estimates that 5,810,667,173 wholly electronic confirmations are sent each year at a cost of $2,266,160,197. Accordingly, Commission staff estimates that the total annual cost associated with generating and delivering to investors the information required under Rule 10b–10 would be $8,417,166,447.

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[3] If the dispute involves Funds that do not have a common Board, the Board of each affected Fund will select an independent arbitrator that is satisfactory to each Fund.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

The public may view background documentation for this information collection at the following Web site: *www.reginfo.gov.* Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: May 4, 2016.

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–10888 Filed 5–9–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. IC–32102; File No. 812–14544]

Capitala Finance Corp., et al.; Notice of Application

May 4, 2016.

AGENCY: Securities and Exchange Commission (“Commission”).

ACTION: Notice of application for an order under sections 17(d) and 57(i) of the Investment Company Act of 1940 (the “Act”) and rule 17d–1 under the Act permitting certain joint transactions otherwise prohibited by sections 17(d) and 57(a)(4) of the Act and under rule 17d–1 under the Act.

SUMMARY OF APPLICATION: Applicants request an order to permit a business development company (“BDC”) and certain closed end investment companies to co-invest in portfolio companies with each other and with affiliated investment funds.

APPLICANTS: Capitala Finance Corp. (the “Company”), Capitala Private Credit Fund I, L.P. (the “Private Fund”), CapitalSouth Partners Fund II Limited Partnership (“Fund II SBIC”), CapitalSouth Partners SBIC Fund III, L.P. (“Fund III SBIC”), and Capitala Investment Advisors, LLC (the “BDC Adviser”), on behalf of itself and its successors.[1]

FILING DATES: The application was filed on September 10, 2015 and amended on February 26, 2016 and April 28, 2016.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on May 31, 2016, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Brent J. Fields, Secretary, U.S. Securities and Exchange Commission, 100 F St. NE., Washington, DC 20549–1090. Applicants: 4201 Congress St., Suite 360, Charlotte, NC 28209.

FOR FURTHER INFORMATION CONTACT: Kay-Mario Vobis, Senior Counsel, at (202) 551–6728, or Mary Kay Frech, Branch Chief, at (202) 551–6821 (Chief Counsel's Office, Division of Investment Management).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Applicants' Representations

1. The Company, a Maryland corporation, is organized as a closed-end management investment company that has elected to be regulated as a BDC within the meaning of section 2(a)(48) of the Act.[2] Applicants state that the Company seeks to generate both current income and capital appreciation through investments in traditional mezzanine and senior subordinated loans; first-lien, senior secured positions in “stretch” senior secured loans; as well as equity interests, either in the form of detachable “penny” warrants or equity co-investments made pari passu with financial sponsors. The board of directors (“Board”) of the Company is comprised of five directors, three of whom are not “interested persons” within the meaning of section 2(a)(19) of the Act (the “Non-Interested Directors”).

2. The Private Fund is organized as a limited partnership under Delaware law, and would be an investment company but for the exclusion from the definition of investment company provided by section 3(c)(7) of the Act. Applicants state that the Private Fund's investment objectives and policies are substantially similar to the Objectives and Strategies of the Company.[3]

3. Fund II SBIC and Fund III SBIC (the “Existing SBIC Subsidiaries”) are Wholly-Owned Investment Subs[4] of the Company. Fund II SBIC was organized as a limited partnership under the laws of the state of North Carolina and Fund III SBIC was organized as a limited partnership under the laws of the state of Delaware. Both were organized to make mezzanine investments, primarily in later-stage, middle-market companies located in the southeastern and middle-Atlantic regions of the United States, and have elected to be regulated as a BDC within the meaning of section 2(a)(48) of the Act.

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[1] The term “successor,” as applied to each Adviser (defined below), means an entity that results from a reorganization into another jurisdiction or change in the type of business organization.

[2] Section 2(a)(48) defines a BDC to be any closed-end investment company that operates for the purpose of making investments in securities described in sections 55(a)(1) through 55(a)(3) of the Act and makes available significant managerial assistance with respect to the issuers of such securities.

[3] “Objectives and Strategies” means a Regulated Fund's (defined below) investment objectives and strategies, as described in the Regulated Fund's registration statement on Form N–2, other filings the Regulated Fund has made with the Commission under the Securities Act of 1933 (the “Securities Act”), or under the Securities Exchange Act of 1934, and the Regulated Fund's reports to shareholders.

[4] The term “Wholly-Owned Investment Sub” means an entity (i) that is wholly-owned by a Regulated Fund (with the Regulated Fund at all times holding, beneficially and of record, 100% of the voting and economic interests); (ii) whose sole business purpose is to hold one or more investments on behalf of the Regulated Fund (and, in the case of an SBIC Subsidiary, maintain a license under the SBA Act and issue debentures guaranteed by the SBA); (iii) with respect to which the Regulated Fund's Board has the sole authority to make all determinations with respect to the entity's participation under the conditions of the application; and (iv) that would be an investment company but for section 3(c)(1) or 3(c)(7) of the Act. An SBIC Subsidiary may be a Wholly-Owned Investment Sub if it satisfies the conditions in this definition. The term “SBIC Subsidiary” means an entity that is licensed by the Small Business Administration (the “SBA”) to operate under the Small Business Investment Act of 1958, as amended, (the “SBA Act”) as a small business investment company.

4. BDC Adviser, a Delaware limited liability company, is registered with the Commission as an investment adviser under the Investment Advisers Act of 1940 (the "Advisers Act") and serves as investment adviser to the Company and the Private Fund.

5. Applicants seek an order ("Order") to permit one or more Regulated Funds[5] and/or one or more Affiliated Funds[6] to participate in the same investment opportunities through a proposed co-investment program (the "Co-Investment Program") where such participation would otherwise be prohibited under section 57(a)(4) and rule 17d–1 by (a) co-investing with each other in securities issued by issuers in private placement transactions in which an Adviser negotiates terms in addition to price;[7] and (b) making additional investments in securities of such issuers, including through the exercise of warrants, conversion privileges, and other rights to purchase securities of the issuers ("Follow-On Investments"). "Co-Investment Transaction" means any transaction in which a Regulated Fund (or its Wholly-Owned Investment Sub) participated together with one or more other Regulated Funds and/or one or more Affiliated Funds in reliance on the requested Order. "Potential Co-Investment Transaction" means any investment opportunity in which a Regulated Fund (or its Wholly-Owned Investment Sub) could not participate together with one or more Affiliated Funds and/or one or more other Regulated Funds without obtaining and relying on the Order.[8]

6. Applicants state that the Company has formed, and any of the Regulated Funds may, from time to time, form one or more Wholly-Owned Investment Subs. Such a subsidiary would be prohibited from investing in a Co-Investment Transaction with any Affiliated Fund or Regulated Fund because it would be a company controlled by its parent Regulated Fund for purposes of section 57(a)(4) and rule 17d–1. Applicants request that each Wholly-Owned Investment Sub be permitted to participate in Co-Investment Transactions in lieu of its parent Regulated Fund and that the Wholly-Owned Investment Sub's participation in any such transaction be treated, for purposes of the requested Order, as though the parent Regulated Fund were participating directly. Applicants represent that this treatment is justified because a Wholly-Owned Investment Sub would have no purpose other than serving as a holding vehicle for the Regulated Fund's investments and, therefore, no conflicts of interest could arise between the Regulated Fund and the Wholly-Owned Investment Sub. The Regulated Fund's Board would make all relevant determinations under the conditions with regard to a Wholly-Owned Investment Sub's participation in a Co-Investment Transaction, and the Regulated Fund's Board would be informed of, and take into consideration, any proposed use of a Wholly-Owned Investment Sub in the Regulated Fund's place. If the Regulated Fund proposes to participate in the same Co-Investment Transaction with any of its Wholly-Owned Investment Subs, the Board will also be informed of, and take into consideration, the relative participation of the Regulated Fund and the Wholly-Owned Investment Sub.

7. When considering Potential Co-Investment Transactions for any Regulated Fund, the applicable Adviser will consider only the Objectives and Strategies, investment policies, investment positions, capital available for investment as described in the application ("Available Capital"), and other pertinent factors applicable to that Regulated Fund. The Board of each Regulated Fund, including the Non-Interested Directors has (or will have prior to relying on the requested Order) determined that it is in the best interests of the Regulated Fund to participate in the Co-Investment Transaction.[9]

8. Other than pro rata dispositions and Follow-On Investments as provided in conditions 7 and 8, and after making the determinations required in conditions 1 and 2(a), the Adviser will present each Potential Co-Investment Transaction and the proposed allocation to the directors of the Board eligible to vote under section 57(o) of the Act ("Eligible Directors"), and the "required majority," as defined in section 57(o) of the Act ("Required Majority")[10] will approve each Co-Investment Transaction prior to any investment by the participating Regulated Fund.

9. With respect to the pro rata dispositions and Follow-On Investments provided in conditions 7 and 8, a Regulated Fund may participate in a pro rata disposition or Follow-On Investment without obtaining prior approval of the Required Majority if, among other things: (i) The proposed participation of each Regulated Fund and Affiliated Fund in such disposition is proportionate to its outstanding investments in the issuer immediately preceding the disposition or Follow-On Investment, as the case may be; and (ii) the Board of the Regulated Fund has approved that Regulated Fund's participation in pro rata dispositions and Follow-On Investments as being in the best interests of the Regulated Fund. If the Board does not so approve, any such disposition or Follow-On Investment will be submitted to the Regulated Fund's Eligible Directors. The Board of any Regulated Fund may at any time rescind, suspend or qualify its approval of pro rata dispositions and Follow-On Investments with the result that all dispositions and/or Follow-On Investments must be submitted to the Eligible Directors.

10. No Non-Interested Director of a Regulated Fund will have a financial interest in any Co-Investment Transaction, other than through share ownership in one of the Regulated Funds.

11. Applicants also represent that if an Adviser or its principals, or any person controlling, controlled by, or under common control with an Adviser or its principals, and the Affiliated Funds (collectively, the "Holders") own in the aggregate more than 25% of the outstanding voting shares of a Regulated Fund (the "Shares"), then the Holders will vote such Shares as required under condition 14.

Applicants' Legal Analysis

1. Section 57(a)(4) of the Act prohibits certain affiliated persons of a BDC from participating in joint transactions with the BDC or a company controlled by a BDC in contravention of rules as prescribed by the Commission. Under

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[5] "Regulated Fund" means the Company and any Future Regulated Fund. "Future Regulated Fund" means any closed-end management investment company (a) that is registered under the Act or has elected to be regulated as BDC, (b) whose investment adviser is an Adviser, and (c) that intends to participate in the Co-Investment Program. The term "Adviser" means (a) BDC Adviser and (b) any future investment adviser that controls, is controlled by or is under common control with BDC Adviser and is registered as an investment adviser under the Advisers Act.

[6] "Affiliated Fund" means the Private Fund and any Future Affiliated Fund. "Future Affiliated Fund" means any entity (a) whose investment adviser is an Adviser, (b) that would be an investment company but for section 3(c)(1) or 3(c)(7) of the Act, and (c) that intends to participate in the Co-Investment Program.

[7] The term "private placement transactions" means transactions in which the offer and sale of securities by the issuer are exempt from registration under the Securities Act.

[8] All existing entities that currently intend to rely upon the requested Order have been named as applicants. Any other existing or future entity that subsequently relies on the Order will comply with the terms and conditions of the application.

[9] The Regulated Funds, however, will not be obligated to invest, or co-invest, when investment opportunities are referred to them.

[10] In the case of a Regulated Fund that is a registered closed-end fund, the Board members that make up the Required Majority will be determined as if the Regulated Fund were a BDC subject to section 57(o).

section 57(b)(2) of the Act, any person who is directly or indirectly controlling, controlled by, or under common control with a BDC is subject to section 57(a)(4). Applicants submit that each of the Regulated Funds and Affiliated Funds could be deemed to be a person related to each Regulated Fund in a manner described by section 57(b) by virtue of being under common control. Section 57(i) of the Act provides that, until the Commission prescribes rules under section 57(a)(4), the Commission's rules under section 17(d) of the Act applicable to registered closed-end investment companies will be deemed to apply to transactions subject to section 57(a)(4). Because the Commission has not adopted any rules under section 57(a)(4), rule 17d–1 also applies to joint transactions with Regulated Funds that are BDCs. Section 17(d) of the Act and rule 17d–1 under the Act are applicable to Regulated Funds that are registered closed-end investment companies.

2. Section 17(d) of the Act and rule 17d–1 under the Act prohibit affiliated persons of a registered investment company from participating in joint transactions with the company unless the Commission has granted an order permitting such transactions. In passing upon applications under rule 17d–1, the Commission considers whether the company's participation in the joint transaction is consistent with the provisions, policies, and purposes of the Act and the extent to which such participation is on a basis different from or less advantageous than that of other participants.

3. Applicants state that in the absence of the requested relief, the Regulated Funds would be, in some circumstances, limited in their ability to participate in attractive and appropriate investment opportunities. Applicants believe that the proposed terms and conditions will ensure that the Co-Investment Transactions are consistent with the protection of each Regulated Fund's shareholders and with the purposes intended by the policies and provisions of the Act. Applicants state that the Regulated Funds' participation in the Co-Investment Transactions will be consistent with the provisions, policies, and purposes of the Act and on a basis that is not different from or less advantageous than that of other participants.

Applicants' Conditions

Applicants agree that the Order will be subject to the following conditions:

1. Each time an Adviser considers a Potential Co-Investment Transaction for an Affiliated Fund or another Regulated Fund that falls within a Regulated Fund's then-current Objectives and Strategies, the Regulated Fund's Adviser will make an independent determination of the appropriateness of the investment for such Regulated Fund in light of the Regulated Fund's then-current circumstances.

2. (a) If the Adviser deems a Regulated Fund's participation in any Potential Co-Investment Transaction to be appropriate for the Regulated Fund, it will then determine an appropriate level of investment for the Regulated Fund.

(b) If the aggregate amount recommended by the applicable Adviser to be invested by the applicable Regulated Fund in the Potential Co-Investment Transaction, together with the amount proposed to be invested by the other participating Regulated Funds and Affiliated Funds, collectively, in the same transaction, exceeds the amount of the investment opportunity, the investment opportunity will be allocated among them pro rata based on each participant's Available Capital, up to the amount proposed to be invested by each. The applicable Adviser will provide the Eligible Directors of each participating Regulated Fund with information concerning each participating party's Available Capital to assist the Eligible Directors with their review of the Regulated Fund's investments for compliance with these allocation procedures.

(c) After making the determinations required in conditions 1 and 2(a), the applicable Adviser will distribute written information concerning the Potential Co-Investment Transaction (including the amount proposed to be invested by each participating Regulated Fund and Affiliated Fund) to the Eligible Directors of each participating Regulated Fund for their consideration. A Regulated Fund will co-invest with one or more other Regulated Funds and/or one or more Affiliated Funds only if, prior to the Regulated Fund's participation in the Potential Co-Investment Transaction, a Required Majority concludes that:

(i) the terms of the Potential Co-Investment Transaction, including the consideration to be paid, are reasonable and fair to the Regulated Fund and its shareholders and do not involve overreaching in respect of the Regulated Fund or its shareholders on the part of any person concerned;

(ii) the Potential Co-Investment Transaction is consistent with:

(A) the interests of the shareholders of the Regulated Fund; and

(B) the Regulated Fund's then-current Objectives and Strategies;

(iii) the investment by any other Regulated Funds or Affiliated Funds would not disadvantage the Regulated Fund, and participation by the Regulated Fund would not be on a basis different from or less advantageous than that of other Regulated Funds or Affiliated Funds; provided that, if any other Regulated Fund or Affiliated Fund, but not the Regulated Fund itself, gains the right to nominate a director for election to a portfolio company's board of directors or the right to have a board observer or any similar right to participate in the governance or management of the portfolio company, such event shall not be interpreted to prohibit the Required Majority from reaching the conclusions required by this condition (2)(c)(iii), if:

(A) the Eligible Directors will have the right to ratify the selection of such director or board observer, if any;

(B) the applicable Adviser agrees to, and does, provide periodic reports to the Regulated Fund's Board with respect to the actions of such director or the information received by such board observer or obtained through the exercise of any similar right to participate in the governance or management of the portfolio company; and

(C) any fees or other compensation that any Affiliated Fund or any Regulated Fund or any affiliated person of any Affiliated Fund or any Regulated Fund receives in connection with the right of an Affiliated Fund or a Regulated Fund to nominate a director or appoint a board observer or otherwise to participate in the governance or management of the portfolio company will be shared proportionately among the participating Affiliated Funds (who each may, in turn, share its portion with its affiliated persons) and the participating Regulated Funds in accordance with the amount of each party's investment; and

(iv) the proposed investment by the Regulated Fund will not benefit the Advisers, the Affiliated Funds or the other Regulated Funds or any affiliated person of any of them (other than the parties to the Co-Investment Transaction), except (A) to the extent permitted by condition 13, (B) to the extent permitted by section 17(e) or 57(k) of the Act, as applicable, (C) indirectly, as a result of an interest in the securities issued by one of the parties to the Co-Investment Transaction, or (D) in the case of fees or other compensation described in condition 2(c)(iii)(C).

3. Each Regulated Fund has the right to decline to participate in any Potential

Co-Investment Transaction or to invest less than the amount proposed.

4. The applicable Adviser will present to the Board of each Regulated Fund, on a quarterly basis, a record of all investments in Potential Co-Investment Transactions made by any of the other Regulated Funds or Affiliated Funds during the preceding quarter that fell within the Regulated Fund's then-current Objectives and Strategies that were not made available to the Regulated Fund, and an explanation of why the investment opportunities were not offered to the Regulated Fund. All information presented to the Board pursuant to this condition will be kept for the life of the Regulated Fund and at least two years thereafter, and will be subject to examination by the Commission and its staff.

5. Except for Follow-On Investments made in accordance with condition 8,[11] a Regulated Fund will not invest in reliance on the Order in any issuer in which another Regulated Fund, Affiliated Fund, or any affiliated person of another Regulated Fund or Affiliated Fund is an existing investor.

6. A Regulated Fund will not participate in any Potential Co-Investment Transaction unless the terms, conditions, price, class of securities to be purchased, settlement date, and registration rights will be the same for each participating Regulated Fund and Affiliated Fund. The grant to an Affiliated Fund or another Regulated Fund, but not the Regulated Fund, of the right to nominate a director for election to a portfolio company's board of directors, the right to have an observer on the board of directors or similar rights to participate in the governance or management of the portfolio company will not be interpreted so as to violate this condition 6, if conditions 2(c)(iii)(A), (B) and (C) are met.

7. (a) If any Affiliated Fund or any Regulated Fund elects to sell, exchange or otherwise dispose of an interest in a security that was acquired in a Co-Investment Transaction, the applicable Advisers will:

(i) Notify each Regulated Fund that participated in the Co-Investment Transaction of the proposed disposition at the earliest practical time; and

(ii) formulate a recommendation as to participation by each Regulated Fund in the disposition.

(b) Each Regulated Fund will have the right to participate in such disposition on a proportionate basis, at the same price and on the same terms and conditions as those applicable to the participating Affiliated Funds and Regulated Funds.

(c) A Regulated Fund may participate in such disposition without obtaining prior approval of the Required Majority if: (i) The proposed participation of each Regulated Fund and each Affiliated Fund in such disposition is proportionate to its outstanding investments in the issuer immediately preceding the disposition; (ii) the Board of the Regulated Fund has approved as being in the best interests of the Regulated Fund the ability to participate in such dispositions on a pro rata basis (as described in greater detail in the application); and (iii) the Board of the Regulated Fund is provided on a quarterly basis with a list of all dispositions made in accordance with this condition. In all other cases, the Adviser will provide its written recommendation as to the Regulated Fund's participation to the Eligible Directors, and the Regulated Fund will participate in such disposition solely to the extent that a Required Majority determines that it is in the Regulated Fund's best interests.

(d) Each Affiliated Fund and each Regulated Fund will bear its own expenses in connection with any such disposition.

8. (a) If any Affiliated Fund or any Regulated Fund desires to make a Follow-On Investment in a portfolio company whose securities were acquired in a Co-Investment Transaction, the applicable Advisers will:

(i) Notify each Regulated Fund that participated in the Co-Investment Transaction of the proposed transaction at the earliest practical time; and

(ii) formulate a recommendation as to the proposed participation, including the amount of the proposed Follow-On Investment, by each Regulated Fund.

(b) A Regulated Fund may participate in such Follow-On Investment without obtaining prior approval of the Required Majority if: (i) The proposed participation of each Regulated Fund and each Affiliated Fund in such investment is proportionate to its outstanding investments in the issuer immediately preceding the Follow-On Investment; and (ii) the Board of the Regulated Fund has approved as being in the best interests of the Regulated Fund the ability to participate in Follow-On Investments on a pro rata basis (as described in greater detail in the application). In all other cases, the Adviser will provide its written recommendation as to the Regulated Fund's participation to the Eligible Directors, and the Regulated Fund will participate in such Follow-On Investment solely to the extent that a Required Majority determines that it is in the Regulated Fund's best interests.

(c) If, with respect to any Follow-On Investment:

(i) The amount of the opportunity is not based on the Regulated Funds' and the Affiliated Funds' outstanding investments immediately preceding the Follow-On Investment; and

(ii) the aggregate amount recommended by the applicable Adviser to be invested by the applicable Regulated Fund in the Follow-On Investment, together with the amount proposed to be invested by the other participating Regulated Funds and Affiliated Funds, collectively, in the same transaction, exceeds the amount of the investment opportunity; then the investment opportunity will be allocated among them pro rata based on each participant's Available Capital, up to the maximum amount proposed to be invested by each.

(d) The acquisition of Follow-On Investments as permitted by this condition will be considered a Co-Investment Transaction for all purposes and subject to the other conditions set forth in this application.

9. The Non-Interested Directors of each Regulated Fund will be provided quarterly for review all information concerning Potential Co-Investment Transactions and Co-Investment Transactions, including investments made by other Regulated Funds or Affiliated Funds that the Regulated Fund considered but declined to participate in, so that the Non-Interested Directors may determine whether all investments made during the preceding quarter, including those investments that the Regulated Fund considered but declined to participate in, comply with the conditions of the Order. In addition, the Non-Interested Directors will consider at least annually the continued appropriateness for the Regulated Fund of participating in new and existing Co-Investment Transactions.

10. Each Regulated Fund will maintain the records required by section 57(f)(3) of the Act as if each of the Regulated Funds were a BDC and each of the investments permitted under these conditions were approved by the Required Majority under section 57(f) of the Act.

11. No Non-Interested Director of a Regulated Fund will also be a director, general partner, managing member or principal, or otherwise an "affiliated person" (as defined in the Act) of an Affiliated Fund.

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[11] This exception applies only to Follow-On Investments by a Regulated Fund in issuers in which that Regulated Fund already holds investments.

12. The expenses, if any, associated with acquiring, holding or disposing of any securities acquired in a Co-Investment Transaction (including, without limitation, the expenses of the distribution of any such securities registered for sale under the Securities Act) will, to the extent not payable by the Advisers under their respective investment advisory agreements with Affiliated Funds and the Regulated Funds, be shared by the Regulated Funds and the Affiliated Funds in proportion to the relative amounts of the securities held or to be acquired or disposed of, as the case may be.

13. Any transaction fee [12] (including break-up or commitment fees but excluding broker's fees contemplated section 17(e) or 57(k) of the Act, as applicable), received in connection with a Co-Investment Transaction will be distributed to the participating Regulated Funds and Affiliated Funds on a pro rata basis based on the amounts they invested or committed, as the case may be, in such Co-Investment Transaction. If any transaction fee is to be held by an Adviser pending consummation of the transaction, the fee will be deposited into an account maintained by such Adviser at a bank or banks having the qualifications prescribed in section 26(a)(1) of the Act, and the account will earn a competitive rate of interest that will also be divided pro rata among the participating Regulated Funds and Affiliated Funds based on the amounts they invest in such Co-Investment Transaction. None of the Affiliated Funds, the Advisers, the other Regulated Funds or any affiliated person of the Regulated Funds or Affiliated Funds will receive additional compensation or remuneration of any kind as a result of or in connection with a Co-Investment Transaction (other than (a) in the case of the Regulated Funds and the Affiliated Funds, the pro rata transaction fees described above and fees or other compensation described in condition 2(c)(iii)(C); and (b) in the case of an Adviser, investment advisory fees paid in accordance with the agreement between the Adviser and the Regulated Fund or Affiliated Fund.

14. If the Holders own in the aggregate more than 25% of the Shares of a Regulated Fund, then the Holders will vote such Shares as directed by an independent third party when voting on (1) the election of directors; (2) the removal of one or more directors; or (3) any other matter under either the Act or applicable State law affecting the Board's composition, size or manner of election.

For the Commission, by the Division of Investment Management, under delegated authority.

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–10889 Filed 5–9–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE., Washington, DC 20549–2736.

Extension:

Rule 19b–4(e) and Form 19b–4(e); SEC File No. 270–447, OMB Control No. 3235–0504.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) the Securities and Exchange Commission ("Commission") has submitted to the Office of Management and Budget ("OMB") a request for approval of extension of the previously approved collection of information provided for in Rule 19b–4(e) (17 CFR 240.19b–4(e)) under the Securities Exchange Act of 1934 (15 U.S.C 78a *et seq.*) (the "Act").

Rule 19b–4(e) permits a self-regulatory organization ("SRO") to list and trade a new derivative securities product without submitting a proposed rule change pursuant to Section 19(b) of the Act (15 U.S.C. 78s(b)), so long as such product meets the criteria of Rule 19b–4(e) under the Act. However, in order for the Commission to maintain an accurate record of all new derivative securities products traded on the SROs, Rule 19b–4(e) requires an SRO to file a summary form, Form 19b–4(e), to notify the Commission when the SRO begins trading a new derivative securities product that is not required to be submitted as a proposed rule change to the Commission. Form 19b–4(e) should be submitted within five business days after an SRO begins trading a new derivative securities product that is not required to be submitted as a proposed rule change. In addition, Rule 19b–4(e) requires an SRO to maintain, on-site, a copy of Form 19b–4(e) for a prescribed period of time.

This collection of information is designed to allow the Commission to maintain an accurate record of all new derivative securities products traded on the SROs that are not deemed to be proposed rule changes and to determine whether an SRO has properly availed itself of the permission granted by Rule 19b–4(e). The Commission reviews SRO compliance with Rule 19b-4(e) through its routine inspections of the SROs.

The respondents to the collection of information are SROs (as defined by the Act), all of which are national securities exchanges. As of January, 2016 there are eighteen entities registered as national securities exchanges with the Commission. The Commission receives an average total of 2,088 responses per year, which corresponds to an estimated annual response burden of 2,088 hours. At an average hourly cost of $64, the aggregate related internal cost of compliance with Rule 19b–4(e) is $133,632 (2,088 burden hours multiplied by $64/hour).

Compliance with Rule 19b-4(e) is mandatory. Information received in response to Rule 19b-4(e) shall not be kept confidential; the information collected is public information.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

The public may view background documentation for this information collection at the following Web site, *www.reginfo.gov.* Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: May 4, 2016.

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–10886 Filed 5–9–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services,

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[12] Applicants are not requesting and the staff is not providing any relief for transaction fees received in connection with any Co-Investment Transaction.

100 F Street NE., Washington, DC 20549–2736.

Extension:

Rule 19d–3; SEC File No. 270–245, OMB Control No. 3235–0204.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) ("PRA"), the Securities and Exchange Commission ("Commission") has submitted to the Office of Management and Budget ("OMB") a request for approval of extension of the previously approved collection of information provided for in Rule 19d–3 (17 CFR 240.19d–3) under the Securities Exchange Act of 1934 (17 U.S.C. 78a *et seq.*).

Rule 19d–3 prescribes the form and content of applications to the Commission by persons seeking Commission review of final disciplinary actions against them taken by self-regulatory organizations ("SROs") for which the Commission is the appropriate regulatory agency. The Commission uses the information provided in the application filed pursuant to Rule 19d–3 to review final actions taken by SROs including: (1) final disciplinary sanctions; (2) denial or conditioning of membership, participation or association; and (3) prohibitions or limitations of access to services offered by a SRO or member thereof.

It is estimated that approximately six respondents will utilize this application procedure annually, with a total burden of approximately 108 hours, for all respondents to complete all submissions. This figure is based upon past submissions. The Commission staff estimates that each respondent will submit approximately one response and the average number of hours necessary to comply with the requirements of Rule 19d–3 is approximately eighteen hours. The average cost per hour, to complete each submission, is approximately $101. Therefore, it is estimated the internal labor cost of compliance for all respondents is approximately $10,908 (6 submissions × 18 hours per response × $101 per hour).

The filing of an application pursuant to Rule 19d–3 is voluntary and does not involve the collection of confidential information. Rule 19d–3 does not have a record retention requirement.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

The public may view background documentation for this information collection at the following Web site: *www.reginfo.gov*. Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503 or by sending an email to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Pamela C. Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov*. Comments must be submitted to OMB within 30 days of this notice.

Dated: May 4, 2016.

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–10887 Filed 5–9–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[File No. 500–1]

In the Matter of Striper Energy, Inc.; Order of Suspension of Trading

May 6, 2016.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Striper Energy, Inc. ("Striper") due to questions regarding the accuracy and adequacy of publicly disseminated information in the company's December 31, 2015 annual report and accompanying financials provided to OTC Markets Group, Inc. ("OTC Markets") concerning, among other things, Striper's operations and financial obligations. Striper is a Florida corporation based in Addison, Texas. Its securities are quoted on OTC Link (previously "Pink Sheets"), operated by OTC Markets, under the ticker symbol "CPCCD."

The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of the above-listed company.

Therefore, it is ordered, pursuant to Section 12(k) of the Securities Exchange Act of 1934, that trading in the securities of the above-listed company is suspended for the period from 9:30 a.m. EDT on May 6, 2016, through 11:59 p.m. EDT on May 19, 2016.

By the Commission.

Lynn M. Powalski,

Deputy Secretary.

[FR Doc. 2016–11065 Filed 5–6–16; 4:15 pm]

BILLING CODE 8011–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: Small Unmanned Aircraft Registration System (sUAS)

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. Aircraft registration is necessary to ensure personal accountability among all users of the national airspace system. Aircraft registration also allows the FAA and law enforcement agencies to address non-compliance by providing the means by which to identify an aircraft's owner and operator.

DATES: Written comments should be submitted by June 9, 2016.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the attention of the Desk Officer, Department of Transportation/FAA, and sent via electronic mail to *oira_submission@omb.eop.gov,* or faxed to (202) 395–6974, or mailed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW., Washington, DC 20503.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

FOR FURTHER INFORMATION CONTACT: Ronda Thompson at (202) 267–1416, or by email at: *Ronda.Thompson@faa.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: 2120–0765.

Title: Small Unmanned Aircraft Registration System (sUAS).

Form Numbers: There are no FAA forms associated with this collection.

Type of Review: Renewal of an information collection.

Background: The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on March 1, 2016 (81 FR 10702). There were no comments. The Secretary of the Department of Transportation (DOT) and the Administrator of the Federal Aviation Administration (FAA) recently affirmed that all unmanned aircraft, including model aircraft, are aircraft. As such, in accordance with 49 U.S.C. 44101(a) and as further prescribed in 14 CFR part 47, registration is required prior to operation. *See* 80 FR 63912, 63913 (October 22, 2015). Aircraft registration is necessary to ensure personal accountability among all users of the national airspace system. *See id.* Aircraft registration also allows the FAA and law enforcement agencies to address non-compliance by providing the means by which to identify an aircraft's owner and operator.

Respondents: Approximately 1.9 million registrants annually.

Frequency: Information is collected on occasion.

Estimated Average Burden per Response: 4.25 minutes.

Estimated Total Annual Burden: 141,158 hours.

Issued in Washington, DC, on May 4, 2016.

Ronda Thompson,

FAA Information Collection Clearance Officer, Performance, Policy & Records Management Branch, ASP–110.

[FR Doc. 2016–10978 Filed 5–9–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: Application for Employment With the Federal Aviation Administration

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval for a new information collection. The information collected is used to collect, process and report Unmanned Aircraft System (UAS) airborne and ground based observations by the public of drone behavior that they consider suspicious or illegal.

DATES: Written comments should be submitted by July 11, 2016.

ADDRESSES: Send comments to the FAA at the following address: Ronda Thompson, Room 441, Federal Aviation Administration, ASP–110, 950 L'Enfant Plaza SW., Washington, DC 20024.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

FOR FURTHER INFORMATION CONTACT: Ronda Thompson at (202) 267–1416, or by email at: *Ronda.Thompson@faa.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: Not assigned.

Title: Unmanned Aircraft System (UAS) Event Reporting System (UETS).

Form Numbers: There are no FAA forms associated with this collection. Information is collected via *www.faa.gov/mobile* external site.

Type of Review: New information collection.

Background: Under the provisions of Public Law 112–95, the Federal Aviation Administration (FAA) was given the authority and the responsibility for assessing the flight behavior of Unmanned Aircraft Systems and enable the reporting of UAS sightings that cause public concern for safety, national security, and/or privacy. The UETS web application will be used to collect, process and report UAS airborne and ground based observations (by the public) of drone behavior that they consider suspicious or illegal.

Respondents: Approximately 6,000 responses annually.

Frequency: Information is collected on occasion.

Estimated Average Burden per Response: 2.75 minutes.

Estimated Total Annual Burden: 275 hours.

Issued in Washington, DC, on May 4, 2016.

Ronda Thompson,

FAA Information Collection Clearance Officer, Performance, Policy, and Records Management Branch, ASP–110.

[FR Doc. 2016–10976 Filed 5–9–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Waivers of Ship Protection Probability of Impact Requirement

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of waivers.

SUMMARY: This notice concerns two petitions for waiver submitted to the FAA by Space Exploration Technologies Corp. (SpaceX): A petition to waive the requirement that a waiver request be submitted at least 60 days before the effective date of the waiver unless good cause for later submission is shown in the petition; and a petition to waive the requirements that exclude persons in waterborne vessels from the collective risk criteria and limit the probability of impact on waterborne vessels to 1×10^{-5}.

FOR FURTHER INFORMATION CONTACT: For technical questions concerning this waiver, contact Paul D. Wilde, Deputy Chief Engineer, Commercial Space Transportation, 800 Independence Avenue SW., Washington, DC 20591; telephone: (202) 267–5727; email: *Paul.Wilde@faa.gov.* For legal questions concerning this waiver, contact Laura Montgomery, Office of the Chief Counsel, Regulations Division, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone (202) 267–3150; email: *Laura.Montgomery@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

On April 1, 2016, SpaceX submitted a petition to the Federal Aviation Administration's (FAA's) Office of Commercial Space Transportation (AST) requesting relief from a regulatory requirement for a launch license for flight of a Falcon 9 launch vehicle carrying SpaceX's Dragon capsule. Specifically, SpaceX requested relief from 14 CFR 417.107(b), which excludes persons in waterborne vessels from the collective risk limit of 30×10^{-6} expected casualties (E_C) and limits the probability of impact with waterborne vessels to 1×10^{-5}.[1] The FAA is treating the request for a waiver to also apply to Appendix B to part 417, paragraph 417.5(a), which requires evacuation and monitoring of hazard areas. The launch operator does not initiate flight until the hazard area clears when the area cannot be evacuated. Because the scheduled launch was planned to occur in less than sixty days, SpaceX also requested a waiver to § 404.3(b)(5), which requires that a petition for waiver be submitted at least sixty days before the proposed effective date of the waiver, which in this case would be the date of the planned launch.

The FAA licenses the launch of a launch vehicle and reentry of a reentry vehicle under authority granted to the Secretary of Transportation in the Commercial Space Launch Act of 1984, as amended and re-codified by 51 U.S.C. Subtitle V, chapter 509 (Chapter 509), and delegated to the FAA Administrator and the Associate Administrator for Commercial Space Transportation, who exercises licensing authority under Chapter 509.

SpaceX is a private commercial space flight company. The petition addresses an upcoming flight that SpaceX plans to undertake to deliver the cargo inside the Dragon capsule to the International Space Station (ISS) as its eighth Commercial Resupply Service mission (CRS–8). SpaceX plans for its Falcon 9 launch vehicle to launch from Cape Canaveral Air Force Station (CCAFS) and fly back the first stage to a barge for landing. During a previous launch of the Falcon 9 from CCAFS to deliver the SES–9 payload to orbit, SpaceX was delayed by the presence of a tug boat towing a large barge inside the ship hazard area in compliance with the FAA's requirement in § 417.107(b) to limit the probability of impact for waterborne vessels to 1×10^{-5}.

Waiver Criteria:

Chapter 509 allows the FAA to waive a license requirement if the waiver (1) will not jeopardize public health and safety, safety of property; (2) will not jeopardize national security and foreign policy interests of the United States; and (3) will be in the public interest. 51 U.S.C. 50905(b)(3) (2011); 14 CFR 404.5(b) (2011).

Section 404.3(b)(5) Waiver Petition

Section 404.3(b)(5) requires that a petition for waiver be submitted at least sixty days before the proposed effective date of the waiver. This section also provides that a petition may be submitted late if the petitioner shows good cause.

Here, SpaceX submitted its waiver petition on April 1, 2016, for the F9 CRS–8 mission, which was less than sixty days from its planned April 8, 2016 launch date. However, SpaceX initially submitted a request on January 19, 2016, for its Falcon 9 launches, which included the CRS and geosynchronous transfer orbit (GTO) missions. In response to the January 19 waiver petition, the FAA informed SpaceX that it was unable to grant that request for relief because the FAA did not have adequate time to complete its evaluation of the petition, but would keep SpaceX abreast of its findings once the evaluation was completed. The FAA has been considering the issues raised since January and is now able to address them, and advised SpaceX of that. Accordingly, the FAA is able to find good cause because SpaceX's January 19 waiver petition covered the F9 CRS missions, including CRS–8.

Section 417.107(b) Waiver Petition

Section 417.107(b) allows a launch operator to initiate flight only if the risk associated with the total flight to all members of the public, excluding persons in waterborne vessels and aircraft, does not exceed an expected average number of 0.00003 casualties ($E_C \leq 30 \times 10^{-6}$) from impacting inert and impacting explosive debris, ($E_C \leq 30 \times 10^{-6}$) for toxic release, ($E_C \leq 30 \times 10^{-6}$) and for far field blast overpressure.

Additionally, a launch operator must implement water borne vessel hazard areas that provide an equivalent level of safety to that provided by water borne vessel hazard areas implemented for launch from a Federal launch range.[2]

Launch of the Falcon 9 Vehicle

The FAA does not need to address SpaceX's request to waive the exclusion of people in waterborne vessels from the risk limits of § 417.107(b). That exclusion is not a requirement that can be waived, but merely a statement that the collective risk requirement does not apply to persons in waterborne vessels. Accordingly, this waiver only addresses the requirement that a launch operator must ensure the probability of impact (Pi) with debris capable of causing a casualty for water borne vessels does not exceed 1×10^{-5}. The FAA grants SpaceX's request for a waiver for the Falcon 9 CRS–8 launch because it is in the public interest and will not jeopardize public health and safety, safety of property, or national security or foreign policy interests of the United States.

i. Public Health and Safety and Safety of Property

The Falcon 9 CRS–8 launch is the ninth launch of an expendable launch vehicle with a Dragon capsule bound for the ISS. SpaceX has attempted three landings of its Falcon 9 first stage on a barge on the ocean off CCAFS. The stages reached their intended landing spot, but did not survive the landings. In no case was public health or safety or safety of third party property jeopardized. The USAF conducted an assessment of the collective risk to people on land due to debris from the CRS–8 launch and has determined that the risks are about half the FAA's current[3] regulatory limit of 30×10^{-6} E_C.

On September 25, 2006, the FAA issued part 417 to amend its commercial space transportation regulations governing the launch of expendable launch vehicles. The FAA requirements in part 417 have their genesis in USAF range safety requirements.

In addition to the public risk criteria provided in § 417.107(b), flight hazard areas were a key element of the performance level requirements in subpart C of 417 to ensure the safety of people on waterborne vessels. Specifically, § 417.223(a) states that *"a flight safety analysis must include a flight hazard area analysis that identifies any regions of land, sea, or air that must be surveyed, publicized, controlled, or evacuated in order to control the risk to the public from debris*

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[1] In 2014, the FAA proposed to clarify the requirements of part 417 concerning hazard areas for ships and aircraft. *Notice of Proposed Rulemaking, Changing the Collective Risk Limits for Launches and Reentries and Clarifying the Risk Limit Used to Establish Hazard Areas for Ships and Aircraft*, 79 FR 42241 (July 21, 2014). The proposed clarification provided in the 2014 NPRM was that "*A launch operator must establish any water borne vessel hazard areas necessary to ensure the probability of impact (Pi) with debris capable of causing a casualty for water borne vessels does not exceed 0.00001 (1×10^{-5}).*" *Id.* at 42253.

[2] In 2014, the FAA proposed a clarification of this requirement. "Under proposed section 417.107(b)(3), a hazard area for water borne vessels would satisfy part 417 if the probability of impact with debris capable of causing a casualty on any given water borne vessel did not exceed 0.00001 (1×10^{-5})." *Id.* at 42244. The FAA explained that § 417.107(b)(3) permits a launch operator to set a hazard-area level of safety that is equivalent to the one used by federal launch ranges with the least burdensome hazard area limit. While each federal launch range has its own safety criteria for hazard areas, the federal launch range with the least burdensome limit for hazard areas imposes a probability of impact (Pi) limit of 1×10^{-5} for water-borne-vessel hazard areas. *Id.* at 42249–50.

[3] In 2014, the FAA proposed to update this requirement as explained in *Changing the Collective Risk Limits for Launches and Reentries and Clarifying the Risk Limit Used to Establish Hazard Areas for Ships and Aircraft, Notice of Proposed Rulemaking*, 79 FR 42241 (July 21, 2014).

impact hazards. The risk management requirements of § 417.205(a) apply." In addition to the performance level requirements of subpart C of part 417, the FAA included several appendices on flight safety analysis methods. Specifically, Appendix B to part 417, paragraph 417.5(a) states that "*a launch operator must perform a launch site hazard area analysis that protects the public, aircraft, and ships from the hazardous activities in the vicinity of the launch site. The launch operator must evacuate and monitor each launch site hazard area to ensure compliance with §§ 417.107(b)(2) and (b)(3).*" The methodology in Appendix B was designed to be consistent with USAF range safety requirements in 2006, and to ensure that the cumulative probability of impact to any ship would not exceed 1×10^{-5} for any debris expected to exceed the kinetic energy or overpressure thresholds established by § 417.107(c).

At the time that part 417 was promulgated, safety experts at NASA[4] believed that it would be desirable to apply collective risk[5] management principles to ship safety by including persons in waterborne vessels in the E_C calculation. However, the computational tools and input data available at that time made it impractical, and posed significant risks to launch operators,[6] to quantify the E_C contribution from people in waterborne vessels. Specifically, the means to survey ship traffic areas potentially threatened by launch debris were much more limited in the 2006 timeframe as explained below. Accordingly, the Federal launch ranges and the FAA adopted the cumulative probability of impact as a surrogate for collective risk and relied on a relatively simplistic approach involving ship hazard areas. Thus, the FAA's current requirements allow launches to proceed with unquantified residual collective risks to people in waterborne vessels.

Since 2006, when the part 417 requirements were promulgated, the capability to compute launch risks to people on waterborne vessels has improved greatly. The U.S. Coast Guard now requires in 33 CFR 164.46 that waterborne vessels above a certain size operate a properly installed and approved Automatic Identification System (AIS), a ship and shore based broadcast system. The AIS, combined with other technological advances, now makes real-time ship information readily available, including the position, course, speed, ship size, identity, and cargo data. The real-time data on waterborne vessels provided by AIS and other advanced surveillance techniques, combined with advanced computer models, now enable valid estimates of the individual and collective risks to people on waterborne vessels to be made during a launch countdown.

The FAA has assessed the input data and probabilistic casualty models that the U.S. Air Force at the 45th Space Wing (45th SW) will use to quantify individual and collective risks to people on waterborne vessels during the launch countdown for the CRS–8 mission. The FAA found that the 45th SW's public risk analyses use accurate data and scientific methods that are mathematically valid, with reasonably conservative assumptions applied in areas where significant uncertainty exists. For example, the 45th SW uses conservative estimates of the number of occupants on waterborne vessels by assuming that the number of persons on board equals the vessel's maximum capacity and that all occupants are on-deck, and thus exposed to debris impacts that might not otherwise pose a threat to people below deck. Additionally, the FAA performed independent analyses using alternative methods to estimate the casualty risks for multiple foreseeable scenarios involving debris impacts on various types of waterborne vessels in the vicinity of Cape Canaveral. The FAA found that large passenger vessels anywhere between the launch point and the first stage disposal zone can contribute significantly to the estimated E_C from the CRS–8 launch. The FAA found that small boats (too small to have AIS required) located close to the launch point should not produce significant individual risks, given conditions expected in the vicinity of Cape Canaveral. Specifically, sufficient surveillance with other means (*e.g.*, radar, and/or using Coast Guard ships or aerial assets) will be used to ensure individual risks comply with the FAA requirement in § 417.107(b)(2). In addition, Notices to Mariners will continue to be issued for the areas where the probability of impact on a ship would exceed 1×10^{-5}, which is current practice at the ER, and required by §§ B417.3 and B417.11. Since the FAA's current requirements allow launches to proceed with unquantified residual collective risks to people in waterborne vessels, as long as the collective risk for people on land from each source of hazard (*i.e.*, debris, toxics, or distant focusing overpressure) does not exceed 30×10^{-6} E_C, and because the launch will not exceed the 30×10^{-6} E_C with the inclusion of persons on water borne vessels, the FAA finds that the Falcon 9 CRS–8 launch will not jeopardize public health and safety or safety of property, and waives 14 CFR 417.107(b)(3) and Appendix B to part 417, paragraph 417.5(a)'s requirement not to initiate flight absent evacuation.

National Security and Foreign Policy Implications

The USAF conducted an assessment of the risk to property on CCAFS, including assets used for national security space missions, and did not identify national security concerns. The FAA has identified no national security or foreign policy implications associated with granting this waiver.

ii. Public Interest

The waiver is consistent with the public interest goals of Chapter 509 and the 2013 National Space Transportation Policy. Three of the public policy goals of Chapter 509 are: (1) To promote economic growth and entrepreneurial activity through use of the space environment; (2) to encourage the United States private sector to provide launch and reentry vehicles and associated services; and (3) to facilitate the strengthening and expansion of the United States space transportation infrastructure to support the full range of United States space-related activities. *See* 51 U.S.C. 50901(b)(1), (2), (4). *Commercial Space Transportation Licensing Regulations, Notice of Proposed Rulemaking,* 62 FR 13230 (Mar. 19, 1997). A successful application of public risk management for the protection of people in waterborne vessels has the potential for reducing launch costs. As it is a major procurer of launch services, reduced launch costs will be of direct benefit to the U.S. Government. It will also help to make the U.S. launch industry more competitive internationally. The 2013

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[4] For example, the NASA Range Safety Policy requirements (NPR8715.5 dated July 8, 2005 in paragraph 3.2.6.2) stated that "an assessment of risk to the public and workforce due to debris shall account for . . . all potential debris, generated intentionally or not, that could cause a casualty, including debris that could affect someone on the ground *or on a waterborne vessel,* or cause an aircraft accident (Requirement)."(emphasis added).

[5] Risk metrics account for both the probability and consequence of foreseeable events. In contrast to the relatively sophisticated casualty consequence models that must be used to compute individual and collective risks according to § 417.107(d), the FAA's current requirements restrict only the probability of impact on waterborne vessels with only simple threshold values to define what constitutes an "impact."

[6] The only known deaths related to launch operations at Cape Canaveral were five occupants of a helicopter that crashed at sea "shortly after 2 a.m., Saturday, April 7, [1984] while flying surface surveillance for the scheduled launch of a Trident 1 missile from the USS Georgia." *See* Air Force News Print Today (Apr. 8, 2011).

National Space Transportation Policy clearly identifies how strengthening U.S. competitiveness in the international launch market and improving the cost effectiveness of U.S. space transportation services are in the public interest: "Maintaining an assured capability to meet United States Government needs, while also taking the necessary steps to strengthen U.S. competitiveness in the international commercial launch market, is important to ensuring that U.S. space transportation capabilities will be reliable, robust, safe, and affordable in the future. Among other steps, improving the cost effectiveness of U.S. space transportation services could help achieve this goal by allowing the United States Government to invest a greater share of its resources in other needs such as facilities modernization, technology advancement, scientific discovery, and national security. Further, a healthier, more competitive U.S. space transportation industry would facilitate new markets, encourage new industries, create high technology jobs, lead to greater economic growth and security, and would further the Nation's leadership role in space." SpaceX's proposal to apply collective risk management to people in waterborne vessels is in the public interest.

Issued in Washington, DC, on April 8, 2016.

Kenneth Wong,

Commercial Space Transportation, Licensing and Evaluation Division Manager.

[FR Doc. 2016–09685 Filed 5–9–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Noise Exposure Map Notice; Receipt of Noise Compatibility Program and Request for Review Boise Air Terminal (Gowen Field) Boise, ID

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Noise Exposure Map notice.

SUMMARY: The Federal Aviation Administration (FAA) announces its determination that the noise exposure maps submitted by the City of Boise, ID for the Boise Air Terminal (Gowen Field), Boise, Idaho under the provisions of 40 U.S.C 47501 *et seq.* (Aviation Safety and Noise Abatement Act) and 14 CFR 150 are in compliance with applicable requirements. The FAA also announces that it is reviewing a proposed noise compatibility program that was submitted for Boise Air Terminal (Gowen Field) under Part 150 in conjunction with the Noise Exposure Map, and that this program will be approved or disapproved on or before October 29, 2016.

DATES: *Effective Date:* The effective date of the FAA's determination on the noise exposure maps and of the start of its review of the associated noise compatibility program is May 2, 2016. The public comment period ends July 1, 2016.

FOR FURTHER INFORMATION CONTACT: Mr. Scott Eaton at the Federal Aviation Administration, FAA Building, Ste. 2, 2725 Skyway Drive, Helena, Montana 59602–1213, Telephone 406–449–5291.

SUPPLEMENTARY INFORMATION: This Notice announces that the FAA finds that the Noise Exposure Maps submitted for Great Falls International Airport are in compliance with applicable requirements of Title 14 Code of Federal Regulations (CFR) Part 150, effective May 2, 2016. Furthermore, FAA is reviewing a proposed noise compatibility program for that Airport which will be approved or disapproved on or before October 29, 2016. This notice also announces the availability of this Program for public review and comment.

Under 49 U.S.C., Section 47503, Aviation Safety and Noise Abatement Act (the Act), an airport operator may submit to the FAA Noise Exposure Maps which meet applicable regulations and which depict non-compatible land uses as of the date of submission of such maps, a description of projected aircraft operations, and the ways in which such operations will affect such maps. The Act requires such maps to be developed in consultation with interested parties in the local community, government agencies, and persons using the airport.

An airport operator who has submitted noise exposure maps that are found by FAA to be in compliance with the requirements of Part 150, promulgated pursuant to the Act, may submit a noise compatibility program for FAA approval which sets forth the measures the operator has taken or proposes to take to reduce existing non-compatible uses and prevent the introduction of additional non-compatible uses.

The City of Boise, ID submitted to the FAA on December 21, 2015 Noise Exposure Maps, descriptions and other documentation that were produced during the Boise Air Terminal (Gowen Field) Airport Part 150 Study conducted between September 16, 2014 and December 21, 2015. It was requested that the FAA review this material as the Noise Exposure Maps, as described in Section 47503 of the Act, and that the noise mitigation measures, to be implemented jointly by the airport and surrounding communities, be approved as a Noise Compatibility Program under Section 47504 of the Act.

The FAA has completed its review of the Noise Exposure Maps and accompanying documentation submitted by the City of Boise, ID. The documentation that constitutes the "noise exposure maps" as defined in CFR part 150 Section 150.7 includes: Boise Airport 14 CFR part 150 Study Update, Updated Noise Exposure Maps, Figure 2–1 Existing Condition Operations by Aircraft Category, Figure 2–2 Future Condition Operations by Aircraft Category, Figure 3–1 Airport Layout, Figure 3–2 Modeled Flight Tracks for Runways 9, 10L and 10R, Figure 3–3 Modeled Flight Tracks for Runways 27, 28L and 28R, Figure 4–1 Airport Influence Area, Figure 4–2 Existing Land Use, Figure 4–3 Future Land Use, Figure 4–4 Zoning in the Vicinity of the Airport, Figure 5–1 2015 Noise Exposure Map on Existing Land Use, Figure 5–2 2020 Noise Exposure Map on Existing Land Use, and Figure 5–3 2020 Noise Exposure Map on Future Land Use. The FAA has determined that these noise exposure maps and accompanying documentation are in compliance with applicable requirements. This determination is effective on May 2, 2016.

The FAA's determination on an airport operator's noise exposure maps is limited to a finding that the maps were developed in accordance with the procedures contained in Appendix A of CFR part 150. Such determination does not constitute approval of the airport operator's data, information or plans, or a commitment to approve a Noise Compatibility Program or to fund implementation of that Program. If questions arise concerning the precise relationship of specific properties to noise exposure contours depicted on a Noise Exposure Map submitted under Section 47503 of the Act, it should be noted that the FAA is not involved in any way in determining the relative locations of specific properties with regard to the depicted noise exposure contours, or in interpreting the Noise Exposure Maps to resolve questions concerning, for example, which properties should be covered by the provisions of Section 47506 of the Act. These functions are inseparable from the ultimate land use control and planning responsibilities of local government. These local responsibilities are not changed in any way under Part 150 or through FAA's review of Noise

Exposure Maps. Therefore, the responsibility for the detailed overlaying of noise exposure contours onto the map depicting properties on the surface rests exclusively with the airport operator that submitted those maps, or those public agencies and planning agencies with which consultation is required under Section 47503 of the Act. The FAA has relied on the certification by the airport operator, under Section 150.21 of Part 150, that the statutorily required consultation has been accomplished.

The FAA has formally received the Noise Compatibility Program for Boise Air Terminal (Gowen Field) Airport, also effective on May 2, 2016. Preliminary review of the submitted material indicates that it conforms to the requirements for the submittal of Noise Compatibility Programs, but that further review will be necessary prior to approval or disapproval of the program. The formal review period, limited by law to a maximum of 180 days, will be completed on or before October 29, 2016.

The FAA's detailed evaluation will be conducted under the provisions of Part 150, Section 150.33. The primary considerations in the evaluation process are whether the proposed measures may reduce the level of aviation safety, create an undue burden on interstate or foreign commerce, or be reasonably consistent with obtaining the goal of reducing existing non-compatible land uses and preventing the introduction of additional non-compatible land uses. Interested persons are invited to comment on the proposed program with specific reference to these factors. All comments, other than those properly addressed to local land use authorities, will be considered by the FAA to the extent practicable.

Copies of the full Noise Exposure Map documentation and the proposed Noise Compatibility Program are available for examination at the following locations:

Scott Eaton, Community Planner, Federal Aviation Administration, Helena Airports District Office, FAA Building, Ste. 2, 2725 Skyway Drive, Helena, MT 59602, 406–449–5291.

Boise Air Terminal (Gowen Field), 3201 Airport Way, Boise, ID 83705.

Questions may be directed to the individual named above under the heading, **FOR FURTHER INFORMATION CONTACT**.

Issued in Renton, Washington, on May 2, 2016.

Randall S. Fiertz,

Manager, Airports Division, Northwest Mountain Region.

[FR Doc. 2016–10981 Filed 5–9–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2016–6596]

Passenger Facility Charge (PFC) Program: Eligibility of Ground Access Projects Meeting Certain Criteria; Correction

AGENCY: Federal Aviation Administration (FAA); DOT.

ACTION: Notice of proposed policy amendment and request for comments; correction.

SUMMARY: This action corrects the notice of proposed policy published on May 3, 2016. In that document, the FAA solicited comments on a proposal to amend its "Notice of Policy Regarding the Eligibility of Airport Ground Access Transportation Projects for Funding Under the Passenger Facility Charge (PFC) Program,"[1] regarding the requirements for PFC funding of on-airport, rail access projects. This document corrects errors in the docket number and contact information.

DATES: May 10, 2016. The comment period will close June 2, 2016.

FOR FURTHER INFORMATION CONTACT: Joe Hebert, Manager, Financial Analysis and Passenger Facility Charge Branch, APP–510, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591, telephone (202) 267–8375; facsimile (202) 267–5302.

SUPPLEMENTARY INFORMATION: On May 3, 2016, the FAA published a notice titled "Notice of Proposed Policy Amendment and Request for Comments" (81 FR 26611). In that Notice, the FAA proposed to change the policy regarding the Passenger Facility Charge eligibility of ground access projects meeting certain criteria. The notice was inadvertently issued without a correct Docket Number and complete contact information.

In FR Doc. 2016–10334, beginning on page 26611 in the **Federal Register**, make the following corrections:

1. On page 26611, in the first column, after Federal Aviation Administration, add Docket No. FAA–2016–6596; and in the first paragraph under **ADDRESSES**, correct Docket Number FAA 2016–XXXX to read Docket No. FAA–2016–6596.

2. On page 26611, in the second column, after **FOR FURTHER INFORMATION CONTACT**, add Joe Hebert, Manager, Financial Analysis and Passenger Facility Charge Branch, APP–510, and on line 8, remove 267–3831 and add in its place 267–8375.

Issued in Washington DC, on May 4, 2016.

Elliott Black,

Director, Office of Airport Planning and Programming.

[FR Doc. 2016–10975 Filed 5–9–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Noise Exposure Map Notice for Harrisburg International Airport, Middletown, Pennsylvania

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice.

SUMMARY: The Federal Aviation Administration (FAA) announces its determination that the noise exposure maps submitted by the Susquehanna Regional Airport Authority for Harrisburg International Airport under the provisions of 49 U.S.C. 47501 et seq. (Aviation Safety and Noise Abatement Act) and 14 CFR part 150 are in compliance with applicable requirements.

DATES: *Effective Date:* The effective date of the FAA's determination on the noise exposure maps is May 3, 2016.

FOR FURTHER INFORMATION CONTACT: Harrisburg Airports District Office (HAR ADO), Susan L. McDonald, Environmental Protection Specialist, Federal Aviation Administration, HAR ADO, 3905 Hartzdale Drive, Suite 508, Camp Hill, PA 17011, Telephone: (717) 730–2830.

SUPPLEMENTARY INFORMATION: This notice announces that the FAA finds that the noise exposure maps submitted for the Harrisburg International Airport are in compliance with applicable requirements of 14 CFR part 150, effective January 13, 2004. Under 49 U.S.C. Section 47503 of the Aviation Safety and Noise Abatement Act (hereinafter referred to as "the Act"), an airport operator may submit to the FAA noise exposure maps which meet applicable regulations and which depict non-compatible land uses as of the date of submission of such maps, a description of projected aircraft operations during a forecast period that is at least five (5) years in the future, and the ways in which such operations will affect such maps. The Act requires such maps to be developed in consultation with interested and affected parties in the local community, government agencies, and persons using the airport. An airport operator who has submitted noise exposure maps that are found by FAA to be in compliance with the requirements of Federal Aviation Regulations (FAR) Part 150, promulgated pursuant to the Act, may submit a noise compatibility program for FAA approval which sets forth the measures the operator has taken or proposes to take to reduce existing non-compatible uses and prevent the introduction of additional non-compatible uses.

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[1] 69 FR 6366 (Feb. 10, 2004).

The FAA has completed its review of the noise exposure maps and accompanying documentation submitted by the Susquehanna Regional Airport Authority. The documentation that constitutes the "Noise Exposure Maps" (NEM) as defined in Section 150.7 of Part 150 includes: 2015 Base Year NEM Figure (3–1) and 2020 Future Year NEM Figure (4–1). The Noise Exposure Maps contain current and forecast information, including the depiction of the airport and its boundaries, the runway configurations, and land uses such as residential, open space, commercial/office, community facilities, libraries, churches, open space, infrastructure, vacant and warehouse and those areas within the Day Night Average Sound Level (DNL) 65, 70 and 75 noise contours. Estimates for the area within these contours for the 2015 Base Year are shown in Table 3–1 and Table 4–1; and in Chapters 3 and 4 of the NEM. Estimates of the future residential population within the 2020 Future Year noise contours are shown in Table 4–1 and in Chapter 4 of the NEM. Appendix E, Figure E–1, displays the location of noise monitoring sites. Flight tracks for the existing and the five-year forecast Noise Exposure Maps are found in Chapter 2 and Appendix F. The type and frequency of aircraft operations (including nighttime operations) are found in Appendix F, Tables F–1 through and F–3. The FAA has determined that these noise exposure maps and accompanying documentation are in compliance with applicable requirements. This determination is effective on May 3, 2016.

FAA's determination on an airport operator's noise exposure maps is limited to a finding that the maps were developed in accordance with the procedures contained in Appendix A of FAR Part 150. Such determination does not constitute approval of the applicant's data, information or plans; or a commitment to approve a noise compatibility program or to fund the implementation of that program. If questions arise concerning the precise relationship of specific properties to noise exposure contours depicted on a noise exposure map submitted under Section 47503 of the Act, it should be noted that the FAA is not involved in any way in determining the relative locations of specific properties with regard to the depicted noise contours, or in interpreting the noise exposure maps to resolve questions concerning, for example, which properties should be covered by the provisions of Section 47506 of the Act. These functions are inseparable from the ultimate land use control and planning responsibilities of local government. These local responsibilities are not changed in any way under Part 150 or through FAA's review of noise exposure maps. Therefore, the responsibility for the detailed overlaying of noise exposure contours onto the map depicting properties on the surface rests exclusively with the airport operator that submitted those maps, or with those public agencies and planning agencies with which consultation is required under Section 47503 of the Act. The FAA has relied on the certification by the airport operator, under Section 150.21 of FAR Part 150, that the statutorily required consultation has been accomplished.

Copies of the full noise exposure map documentation and of the FAA's evaluation of the maps are available for examination at the following locations:

Federal Aviation Administration, Eastern Region, Airports Division, AEA–600, 1 Aviation Plaza, Jamaica, New York 11434.

Federal Aviation Administration, Harrisburg Airports District Office, 3905 Hartzdale Drive, Suite 508, Camp Hill, PA 17011.

Susquehanna Area Regional Aiport Authority, One Terminal Drive, Suite 300, Middletown, PA 17057.

FOR FURTHER INFORMATION CONTACT: Harrisburg Airports District Office (HAR ADO), Susan L. McDonald, Environmental Protection Specialist, Federal Aviation Administration, HAR ADO, 3905 Hartzdale Drive, Suite 508, Camp Hill, PA 17011, Telephone: (717) 730–2830.

Issued in Camp Hill, PA on May 3, 2016.

Lori K. Pagnanelli,

Manager, Harrisburg Airports District Office, Eastern Region.

[FR Doc. 2016–10979 Filed 5–9–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2015–0123; Notice 2]

Volkswagen Group of America, Grant of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Grant of petition.

SUMMARY: Volkswagen Group of America (Volkswagen) has determined that certain model year (MY) 2015–2016 Volkswagen passenger cars do not fully comply with paragraph S4.3(c) and S4.3(d) of Federal Motor Vehicle Safety Standard (FMVSS) No. 110, *Tire Selection and Rims and Motor Home/ Recreation Vehicle Trailer Load Carrying Capacity Information for Motor Vehicles with a GVWR of 4,536 kilograms (10,000 pounds) or Less.* Volkswagen filed a report dated November 25, 2015, pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports.* Volkswagen then petitioned NHTSA under 49 CFR part 556 requesting a decision that the subject noncompliance is inconsequential to motor vehicle safety.

ADDRESSES: For further information on this decision contact Kerrin Bressant, Office of Vehicles Safety Compliance, the National Highway Traffic Safety Administration (NHTSA), telephone (202) 366–1110, facsimile (202) 366–3081.

SUPPLEMENTARY INFORMATION:

I. Overview

Pursuant to 49 U.S.C. 30118(d) and 30120(h) and the rule implementing those provisions at 49 CFR part 556, Volkswagen submitted a petition for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential to motor vehicle safety. Notice of receipt of the petition was published, with a 30-day public comment period, on March 1, 2016 in the **Federal Register** (81 FR 10715). Two comments were received.

II. Vehicles Involved

Affected are approximately 4,965 MY 2015–2016 Volkswagen e-Golf passenger vehicles that were manufactured between May 21, 2014 and November 14, 2015 and approximately 4,618 MY 2015–2016 Volkswagen Golf R passenger vehicles that were manufactured between October 24, 2014 and November 14, 2015.

III. Noncompliance

Volkswagen explains that the noncompliance is that the tire placard does not contain the word "none" in the area reserved for the spare tire specifications as required by paragraphs S4.3(c) and S4.3(d) of FMVSS No. 110.

IV. Rule Text

Paragraphs S4.3(c) and (d) of FMVSS No. 110 require in pertinent part:

> S4.3 Placard. Each vehicle, except for a trailer or incomplete vehicle, shall show the information specified in S4.3(a) through (g), and may show, at the manufacturer's option, the information specified in S4.3(h) and (i), on a placard permanently affixed to the driver's side B-pillar. . . .
>
> (c) Vehicle manufacturer's recommended cold tire inflation pressure for front, rear and spare tires, subject to the limitations of S4.3.4. For full size spare tires, the statement "see above" may, at the manufacturer's option replace manufacturer's recommended cold tire inflation pressure. If no spare tire is provided, the word "none" must replace the manufacturer's recommended cold tire inflation pressure.
>
> (d) Tire size designation, indicated by the headings "size" or "original tire size" or "original size," and "spare tire" or "spare," for the tires installed at the time of the first purchase for purposes other than resale. For full size spare tires, the statement "see above" may, at the manufacturer's option replace the tire size designation. If no spare tire is provided, the word "none" must replace the tire size designation;

V. Summary of Volkswagen's Analyses

Volkswagen stated its belief that the subject noncompliance is inconsequential to motor vehicle safety for the following reasons:

(A) Volkswagen stated that the misprinted information on the tire placard is applicable to a component (spare tire) that was not provided with the subject vehicles.

(B) Volkswagen explained that there is no effect on drivability, vehicle safety or tire wear.

(C) Volkswagen stated that it is not aware of any field or customer complaints related to the subject non-compliance.

In summation, Volkswagen believes that the described noncompliance of the subject vehicles is inconsequential to motor vehicle safety, and that its petition, to exempt Volkswagen from providing recall notification of noncompliance as required by 49 U.S.C. 30118 and remedying the recall noncompliance as required by 49 U.S.C. 30120 should be granted.

NHTSA's Decision

NHTSA's Analysis: Volkswagen explained that the tire placards on the affected "e-Golf" and "Golf R" vehicles do not contain the required word "none" in the spaces used to provide the spare tire information (size and cold tire pressure) since no actual spare tires were provided with these vehicles. On the "e-Golf" vehicles, the placard indicates dashes ("- - -") instead of the word "none" in both the spare tire size and cold tire pressure spaces. On the "Golf R" vehicles, the placard identifies the spare tire size as "T125/70R18" and a cold tire pressure of "420KPA, 61 PSI" instead of the word "none" in both spaces. Volkswagen stated its belief that the subject mislabeling has no actual effect on the vehicle's drivability, safety or tire wear.

During the receipt notice comment period NHTSA received comments from two individuals. Both individuals believed Volkswagen's noncompliance is inconsequential to motor vehicle safety. The first individual stated that the vehicle owner will know, or learn, that the vehicle was not equipped with a spare tire and mentioned that NHTSA has approved a similar petition from General Motors. The second individual stated that he agrees with Volkswagen's reasoning and that the error is truly inconsequential to the safety of the consumer and not detrimental to the performance of the vehicles.

In consideration of the e-golf vehicles where the placard uses dashes instead of the word "none", The agency believes the dashes will be interpreted to mean no spare tire was provided with the vehicle. Vehicle owners will confirm their vehicles are not equipped with a spare tire if, or when, there is a need for one. While some owners may find this inconvenient, manufacturers are not required to provide spare tires with vehicles they manufacture and sell. Therefore, the agency agrees with Volkswagen and the commenters that this noncompliance is inconsequential to motor vehicle safety.

In consideration of the Golf R vehicles where the placard specifies an actual spare tire size and cold inflation pressure (T125/70R18 @420kPa/61PSI) instead of the word "none": The agency reviewed the load carrying capacity associated with that tire size and inflation pressure combination to ensure that it could meet the load requirements for the vehicle's maximum loading, as specified by FMVSS No. 110, in the event that a vehicle owner were to purchase and use that size tire on the subject vehicle. If the spare tire information listed on the placard was found to represent a tire and inflation pressure combination inappropriate for the Golf R vehicles, the agency would consider this noncompliance as consequential to motor vehicle safety. However, that was not the case, the subject spare tire T125/70R18 at a cold tire inflation pressure of 61 PSI has a much higher load carrying capacity than the front and rear tires listed on the placard at the listed inflation pressure (775 kg versus 580 kg[1]). In addition, similar to the e-Golf owners, the Golf R vehicle owners will be able to confirm that their vehicles are not equipped with a spare tire if, or when, there is a need for one. Therefore, in the case of the Golf R vehicles, the agency also agrees with Volkswagen and the commenters that this noncompliance is inconsequential to motor vehicle safety.

Lastly, Volkswagen stated that they are not aware of any consumer complaints, field communications, related to this noncompliance. Volkswagen informed NHTSA that it has corrected the noncompliances of the subject vehicles so that all production vehicles on and after November 15, 2015 will fully comply with FMVSS No. 110.

NHTSA's Decision: In consideration of the foregoing analysis, NHTSA finds that Volkswagen has met its burden of demonstrating that the subject FMVSS No. 110 noncompliance in the affected vehicles is inconsequential to motor vehicle safety. Accordingly, Volkswagen's petition is hereby granted and Volkswagen is exempted from the obligation of providing notification of, and a free remedy for, that noncompliance under 49 U.S.C. 30118 and 30120.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, any decision on this petition only applies to the subject vehicles that Volkswagen no longer controlled at the time it determined that the noncompliance existed. However, any decision on this petition does not relieve vehicle distributors and dealers of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant vehicles under their control after Volkswagen notified them that the subject noncompliance existed.

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[1] The European Tyre and Rim Technical Organisation, Standards Manual, 2015

Authority: 49 U.S.C. 30118, 30120: Delegations of authority at 49 CFR 1.95 and 501.8.

Jeffrey M. Giuseppe,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2016–10916 Filed 5–9–16; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Additional Designations, Foreign Narcotics Kingpin Designation Act

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of eight individuals and 69 entities whose property and interests in property have been blocked pursuant to the Foreign Narcotics Kingpin Designation Act (Kingpin Act), 21 U.S.C. 1901–1908, 8 U.S.C. 1182.

DATES: The designations by the Acting Director of OFAC of the eight individuals and 69 entities identified in this notice pursuant to section 805(b) of the Kingpin Act are effective on May 5, 2016.

FOR FURTHER INFORMATION CONTACT: Assistant Director, Sanctions Compliance & Evaluation, Office of Foreign Assets Control, U.S. Department of the Treasury, Washington, DC 20220, Tel: (202) 622–2490.

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

This document and additional information concerning OFAC are available on OFAC's Web site at *http://www.treasury.gov/ofac* or via facsimile through a 24-hour fax-on-demand service at (202) 622–0077.

Background

The Kingpin Act became law on December 3, 1999. The Kingpin Act provides a statutory framework for the imposition of sanctions against significant foreign narcotics traffickers and their organizations on a worldwide basis, with the objective of denying their businesses and agents access to the U.S. financial system and the benefits of trade and transactions involving U.S. companies and individuals.

The Kingpin Act blocks all property and interests in property, subject to U.S. jurisdiction, owned or controlled by significant foreign narcotics traffickers as identified by the President. In addition, the Kingpin Act provides that the Secretary of the Treasury, in consultation with the Attorney General, the Director of the Central Intelligence Agency, the Director of the Federal Bureau of Investigation, the Administrator of the Drug Enforcement Administration, the Secretary of Defense, the Secretary of State, and the Secretary of Homeland Security, may designate and block the property and interests in property, subject to U.S. jurisdiction, of persons who are found to be: (1) Materially assisting in, or providing financial or technological support for or to, or providing goods or services in support of, the international narcotics trafficking activities of a person designated pursuant to the Kingpin Act; (2) owned, controlled, or directed by, or acting for or on behalf of, a person designated pursuant to the Kingpin Act; or (3) playing a significant role in international narcotics trafficking.

On May 5, 2016, the Acting Director of OFAC designated the following eight individuals and 69 entities whose property and interests in property are blocked pursuant to section 805(b) of the Kingpin Act.

Individuals

1. CASTRO MONTOTO, Norman Douglas; DOB 06 Jul 1962; citizen Panama; Passport 1871296 (Panama) (individual) [SDNTK] (Linked To: WAKED MONEY LAUNDERING ORGANIZATION). Designated for materially assisting in, or providing financial or technological support for or to, or providing goods or services in support of, the international narcotics trafficking activities of the WAKED MONEY LAUNDERING ORGANIZATION and/or Nidal Ahmed WAKED HATUM, and/or being controlled or directed by, or acting for or on behalf of, the WAKED MONEY LAUNDERING ORGANIZATION and/or Nidal Ahmed WAKED HATUM, and therefore meets the criteria for designation pursuant to sections 805(b)(2) and/or (3) of the Kingpin Act, 21 U.S.C. 1904(b)(2) and/or (3).

2. TOUZARD ROMO, Lucia, Ave. Samuel Lewis y Calle 54, Urb. Obarrio Torre Generali, piso 11, Apartado 0831–02–513, Panama, Panama; DOB 24 Jan 1971; POB Panama; citizen Panama; Passport 0159068 (Panama) (individual) [SDNTK] (Linked To: WAKED MONEY LAUNDERING ORGANIZATION). Designated for materially assisting in, or providing financial or technological support for or to, or providing goods or services in support of, the international narcotics trafficking activities of the WAKED MONEY LAUNDERING ORGANIZATION and/or Abdul Mohamed WAKED FARES, and/or being controlled or directed by, or acting for or on behalf of, Abdul Mohamed WAKED FARES, Mohamed Abdo WAKED DARWICH, and/or GRUPO WISA, S.A., and therefore meets the criteria for designation pursuant to sections 805(b)(2) and/or (3) of the Kingpin Act, 21 U.S.C. 1904(b)(2) and/or (3).

3. WAKED DARWICH, Mohamed Abdo (a.k.a. WAKED DARWICH, Hamudi); DOB 30 Aug 1977; POB Colombia; citizen Panama; Cedula No. N–19–828 (Panama) (individual) [SDNTK] (Linked To: WAKED MONEY LAUNDERING ORGANIZATION). Designated for being controlled or directed by, or acting for or on behalf of, the WAKED MONEY LAUNDERING ORGANIZATION and Abdul Mohamed WAKED FARES, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

4. WAKED FARES, Abdul Mohamed; DOB 19 Dec 1949; alt. DOB 09 Dec 1949; POB Kamed El Louz, Lebanon; citizen Panama; alt. citizen Lebanon; alt. citizen Colombia; Cedula No. N–19–804 (Panama); Passport 1640816 (Panama) (individual) [SDNTK] (Linked To: WAKED MONEY LAUNDERING ORGANIZATION). Designated for playing a significant role in international narcotics trafficking, and therefore meets the criteria for designation pursuant to section 805(b)(4) of the Kingpin Act, 21 U.S.C. 1904(b)(4).

5. WAKED HATUM, Jalal Ahmed (a.k.a. WAKED HATOUM, Jalal); DOB 18 Oct 1976; POB Colombia; citizen Panama; alt. citizen Colombia; Cedula No. 3–700–2344 (Panama); Passport 0091672 (Panama); alt. Passport 1426177 (Panama); alt. Passport 1706460 (Panama) (individual) [SDNTK] (Linked To: WAKED MONEY LAUNDERING ORGANIZATION). Designated for materially assisting in, or providing financial or technological support for or to, or providing goods or services in support of, the international narcotics trafficking activities of the WAKED MONEY LAUNDERING ORGANIZATION and/or Nidal Ahmed WAKED HATUM, and/or being controlled or directed by, or acting for or on behalf of, the WAKED MONEY LAUNDERING ORGANIZATION and/or Nidal Ahmed WAKED HATUM, and therefore meets the criteria for designation pursuant to sections 805(b)(2) and/or (3) of the Kingpin Act, 21 U.S.C. 1904(b)(2) and/or (3).

6. WAKED HATUM, Ali; DOB 28 Aug 1972; Cedula No. N–19–612 (Panama) (individual) [SDNTK] (Linked To: WAKED MONEY LAUNDERING ORGANIZATION). Designated for materially assisting in, or providing financial or technological support for or to, or providing goods or services in support of, the international narcotics trafficking activities of the WAKED MONEY LAUNDERING ORGANIZATION and/or Nidal Ahmed WAKED HATUM, and/or being controlled or directed by, or acting for or on behalf of, the WAKED MONEY LAUNDERING ORGANIZATION and/or Nidal Ahmed WAKED HATUM, and therefore meets the criteria for designation pursuant to sections 805(b)(2) and/or (3) of the Kingpin Act, 21 U.S.C. 1904(b)(2) and/or (3).

7. WAKED HATUM, Gazy (a.k.a. WAKED HATUM, Ghazi); DOB 17 Sep 1973; POB Colombia; citizen Colombia; Cedula No. N–19624 (Panama) (individual) [SDNTK] (Linked To: WAKED MONEY LAUNDERING ORGANIZATION). Designated for materially assisting in, or providing financial or technological support for or to, or providing goods or services in support of, the international narcotics trafficking activities of the WAKED MONEY LAUNDERING ORGANIZATION and/or Nidal Ahmed WAKED HATUM, and/or being controlled or directed by, or acting for or on behalf of, the WAKED MONEY LAUNDERING ORGANIZATION and/or Nidal Ahmed WAKED HATUM, and therefore meets the criteria for designation pursuant to sections 805(b)(2) and/or (3) of the Kingpin Act, 21 U.S.C. 1904(b)(2) and/or (3).

8. WAKED HATUM, Nidal Ahmed (a.k.a. WAKED HATOUM, Nidal); DOB 26 Jul 1971; alt. DOB 16 Jul 1971; alt. DOB 02 Aug 1971; POB Barranquilla, Colombia; citizen Spain; alt. citizen Colombia; alt. citizen Panama; Cedula No. N–19–680 (Panama); Passport 1000272479 (Panama); alt. Passport AAI105713 (Spain); National ID No. 0662764600 (Spain); alt. National ID No. A06627646N (Spain) (individual) [SDNTK] (Linked To: WAKED MONEY LAUNDERING ORGANIZATION). Designated for playing a significant role in international narcotics trafficking, and therefore meets the criteria for designation pursuant to section 805(b)(4) of the Kingpin Act, 21 U.S.C. 1904(b)(4).

Entities

1. A.M. WAKED E HIJOS, S.A., Panama; RUC #26961–10–226532 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Abdul Mohamed WAKED FARES, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

2. ABIF INVESTMENT, S.A., Panama; RUC #2022799–1–743641 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Abdul Mohamed WAKED FARES and/or Mohamed Abdo WAKED DARWICH, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

3. ADJUSTMENT BUSINESS CORP., Panama; RUC #264715–1–405109 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Nidal Ahmed WAKED HATUM and/or Gazy WAKED HATUM, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

4. ADMINISTRACION MILLENIUM PLAZA, S.A., Panama; RUC #1050723–1–547544 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Nidal Ahmed WAKED HATUM, Gazy WAKED HATUM, Jalal Ahmed WAKED HATUM, and/or Ali WAKED HATUM, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

5. ALBORADA GARDENS, S.A., Panama; RUC #1992533–1–738897 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Nidal Ahmed WAKED HATUM, Gazy WAKED HATUM, and/or Ali WAKED HATUM, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

6. ALBORADA S.A., Panama; RUC #63628–51–355574 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Nidal Ahmed WAKED HATUM and/or Ali WAKED HATUM, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

7. BIENES RAICES DEL CARIBE, S.A., Panama; RUC #72212–1–374180 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Nidal Ahmed WAKED HATUM and/or Ali WAKED HATUM, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

8. CACIQUE 1 S.A., Panama; RUC #155598483–2–2015 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Jalal Ahmed WAKED HATUM and/or Gazy WAKED HATUM, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

9. CORPORACION MARITIMA DE COLON, S.A., Panama; RUC #44053–63–293930 (Panama); alt. RUC #44503–63–293930 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Nidal Ahmed WAKED HATUM and/or Gazy WAKED HATUM, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

10. DESARROLLO URBANISTICO DEL ATLANTICO, S.A. (a.k.a. D.U.A.S.A.), Panama; RUC #30564–13–239335 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Nidal Ahmed WAKED HATUM, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

11. DISTRIBUIDORA MARBELLA, S.A., Panama; RUC #11542–26–115837 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Abdul Mohamed WAKED FARES and/or Ali WAKED HATUM, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

12. FELIX B. MADURO S.A., Panama; RUC #811226–1–498041 (Panama); alt. RUC #78–273–13798 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by GRUPO WISA, S.A., Abdul Mohamed WAKED FARES, and/or Mohamed Abdo WAKED DARWICH, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

13. FOOD COURT PLAZA MILENIO, S.A., Panama; RUC #1103474–1–560398 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Nidal Ahmed WAKED HATUM, Gazy WAKED HATUM, Jalal Ahmed WAKED HATUM, and/or Ali WAKED HATUM, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

14. FRANQUICIAS MULTIPLES S.A., Panama; RUC #1874692–1–717842 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Nidal Ahmed WAKED HATUM, Gazy WAKED HATUM, Jalal Ahmed WAKED HATUM, and/or Ali WAKED HATUM, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

15. GLENDOR FINANCE S.A., Panama; RUC #2041747–1–746484 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Mohamed Abdo WAKED DARWICH, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

16. GRUPO CEDRO PANAMA S.A.; RUC #2039933–1–746238 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Abdul Mohamed WAKED FARES and/or Mohamed Abdo WAKED DARWICH, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

17. GRUPO CIMA PANAMA, S.A., Calle 15 Y Avenida Roosevelt, Colon Free Zone, Panama; PO Box 3294, Panama City, Panama; RUC #408392–1–425571 (Panama); alt. RUC #425571–1–408392 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Mohamed Abdo WAKED DARWICH, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

18. GRUPO LA RIVIERA PANAMA, S.A., Panama; RUC #2038708–1–745998 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Abdul Mohamed WAKED FARES and/or Mohamed Abdo WAKED DARWICH, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

19. HACIENDA PAULISTA, S.A., Panama; RUC #466985–1–433708 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Gazy WAKED HATUM and/or Ali WAKED HATUM, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

20. HERMANOS WAKED, S.A., Panama; RUC #466694–1–433666 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Nidal Ahmed WAKED HATUM, Gazy WAKED HATUM, and/or Ali WAKED HATUM, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

21. HN Y N (HOT NEWS Y NEWS) PUBLICIDAD, S.A., Panama; RUC #715153–1–471751 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Ali WAKED HATUM, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

22. HOTELERA MUNDIAL, S.A., Panama; RUC #22515–10–201355 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Nidal Ahmed WAKED HATUM and/or Ali WAKED HATUM, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

23. IMPORTADORA MADURO, S.A., Panama; RUC #558–472–101708 (Panama)

[SDNTK]. Designated for being owned, controlled, or directed by GRUPO WISA, S.A., Abdul Mohamed WAKED FARES, and/or Mohamed Abdo WAKED DARWICH, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

24. INMOBILIARIA J & M CORP (a.k.a. INMOBILIARIA J AND M CORP), Panama; RUC #884675–1–511785 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Jalal Ahmed WAKED HATUM, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

25. INMOBILIARIA MULTI–TIENDAS, S.A., Panama; RUC #1008619–1–537654 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Mohamed Abdo WAKED DARWICH and/or Lucia TOUZARD ROMO, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

26. INMOBILIARIA ROYPAL, S.A., Panama; RUC #46966–79–305611 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Abdul Mohamed WAKED FARES, Lucia TOUZARD ROMO, and/or Mohamed Abdo WAKED DARWICH, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

27. INVERSIONES DEL ATLANTICO, LTD., Panama; RUC #951371–1–526012 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Nidal Ahmed WAKED HATUM, Ali WAKED HATUM, Gazy WAKED HATUM, and/or Jalal Ahmed WAKED HATUM, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

28. INVERSIONES LDT, S.A., Panama; RUC #40136–117–278301 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Ali WAKED HATUM, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

29. INVERSIONES MP, S.A., Panama; RUC #1603791–1–666816 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Nidal Ahmed WAKED HATUM, Gazy WAKED HATUM, and/or Ali WAKED HATUM, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

30. LA GRAN BODEGA, S.A., Panama; RUC #580601–1–448114 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Nidal Ahmed WAKED HATUM and/or Gazy WAKED HATUM, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

31. LA GRAN VIA ZONA LIBRE, S.A., Panama; RUC #26025–152–221903 (Panama); alt. RUC #26025–152–221909 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Gazy WAKED HATUM and/or Ali WAKED HATUM, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

32. LA RIVIERA, PANAMA, S.A., Panama; RUC #556399–1–444264 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Mohamed Abdo WAKED DARWICH and/or Lucia TOUZARD ROMO, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

33. LAGUNA MAR INTERNACIONAL, S.A., Panama; RUC #212214–1–397111 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Abdul Mohamed WAKED FARES and/or Mohamed Abdo WAKED DARWICH, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

34. MADURO INTERNACIONAL, S.A., Panama; RUC #5651–184–69069 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Abdul Mohamed WAKED FARES and/or Mohamed Abdo WAKED DARWICH, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

35. MALALA 786, S.A., Panama; RUC #2300164–1–789790 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Abdul Mohamed WAKED FARES, Mohamed Abdo WAKED DARWICH, and/or Lucia TOUZARD ROMO, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

36. MAWA ENTERPRISES, CORP., Panama; RUC #37255–145–266651 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Abdul Mohamed WAKED FARES, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

37. MEDAL INVERSIONES, S.A., Panama; RUC #62962–44–353646 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Nidal Ahmed WAKED HATUM and/or Gazy WAKED HATUM, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

38. NARANJO ABAJO, S.A., Panama; RUC #657–564–1462 (Panama); alt. RUC #657–564–14620 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Nidal Ahmed WAKED HATUM, Gazy WAKED HATUM, Jalal Ahmed WAKED HATUM, and/or Ali WAKED HATUM, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

39. NUTRISHOP, S.A., Panama; RUC #1013362–1–538789 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Jalal Ahmed WAKED HATUM, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

40. PANAMA BIG GAME FISHING, S.A., Panama; RUC #1538534–1–655100 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Gazy WAKED HATUM and/or Ali WAKED HATUM, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

41. PANAMA–CHILE INTERNACIONAL, S.A., Panama; RUC #883961–1–511666 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Nidal Ahmed WAKED HATUM, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

42. PANLI HOLDINGS, INC., Panama; RUC #144868–1–384842 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Abdul Mohamed WAKED FARES and/or Mohamed Abdo WAKED DARWICH, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

43. PLAZA MILENIO, S.A. (a.k.a. MILLENNIUM PLAZA, S.A.), Panama; RUC #15280–1–366202 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Nidal Ahmed WAKED HATUM, Gazy WAKED HATUM, Jalal Ahmed WAKED HATUM, and/or Ali WAKED HATUM, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

44. RESCATES MARINOS, S.A., Panama; RUC #1192450–1–580499 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Nidal Ahmed WAKED HATUM and/or Norman Douglas CASTRO MONTOTO, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

45. RESIDENCIAL CANAL VIEW, S.A., Panama; RUC #22723–133–202910 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Gazy WAKED HATUM and/or Ali WAKED HATUM, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

46. SEGOVIA IMPORT & EXPORT CORP. (a.k.a. SEGOVIA IMPORT AND EXPORT CORP.), Panama; RUC #1153864–1–572287 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Nidal Ahmed WAKED HATUM, Gazy WAKED HATUM, and/or Ali WAKED HATUM, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

47. SERVICIO DE EQUIPO RODANTE INCORPORADO (a.k.a. SER INC.), Calle 16 y Ave. Roosevelt Edif. Vida Panama, Zona Libre, Colon, Panama; P.O. Box No. 1578, Zona Libre, Colon, Panama; RUC #16143–166–154062 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Nidal Ahmed WAKED HATUM and/or Gazy WAKED HATUM, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

48. SISTEMA CORESCO, S.A., Panama; RUC #59784–2–345231 (Panama); alt. RUC #1776589–1–345231 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Ali WAKED HATUM, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

49. SOHO DEVELOPERS, INC., Panama; RUC #2046910–1–747341 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by WESTLINE ENTERPRISES, Abdul Mohamed WAKED

FARES, and/or Mohamed Abdo WAKED DARWICH, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

50. SOHO PANAMA, S.A. (a.k.a. SOHO MALL PANAMA), Calle 50 (entre Calle 54 y 56), Panama, Panama; RUC #2422734–1–808115 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Abdul Mohamed WAKED FARES and/or Mohamed Abdo WAKED DARWICH, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

51. TATUNG INTERNACIONAL, S.A., Panama; RUC #41534–72–284178 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Nidal Ahmed WAKED HATUM, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

52. TROLL PROPERTIES, INC., Panama; RUC #991715–1–534344 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Mohamed Abdo WAKED DARWICH, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

53. URBANIZACION ALHAMBRA, S.A., Panama; RUC #998416–1–535687 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Jalal Ahmed WAKED HATUM, Gazy WAKED HATUM, and/or Ali WAKED HATUM, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

54. V.P. PROPERTIES, INC., Panama; RUC #2384195–1–802594 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Nidal Ahmed WAKED HATUM, Gazy WAKED HATUM, Jalal Ahmed WAKED HATUM, and/or Ali WAKED HATUM, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

55. VISION 20–20, S.A., Panama; RUC #2107640–1–757913 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Abdul Mohamed WAKED FARES and/or Mohamed Abdo WAKED DARWICH, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

56. WAKED INTERNACIONAL PANAMA, S.A., Panama; RUC #197517–1–394851 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Abdul Mohamed WAKED FARES and/or Lucia TOUZARD ROMO, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

57. WAREHOUSE OUTLETS, S.A., Panama; RUC #61872–33–350508 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Mohamed Abdo WAKED DARWICH and/or Lucia TOUZARD ROMO, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

58. WAYSIDE CORPORATION, Panama; RUC #10415–108–106338 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Abdul Mohamed WAKED FARES, Mohamed Abdo WAKED DARWICH, and/or Lucia TOUZARD ROMO, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

59. WESTLINE ENTERPRISES, INC., Panama; RUC #1351606–1–617448 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Abdul Mohamed WAKED FARES and/or Mohamed Abdo WAKED DARWICH, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

60. XZACT, INC., Panama; RUC #697297–1–467988 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by Nidal Ahmed WAKED HATUM, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

61. BALBOA BANK & TRUST, CORP. (a.k.a. BALBOA BANK AND TRUST, CORP.), Edificio Balboa Bank & Trust, Calle 50 y Calle Beatriz Maria Cabal, Panama, Panama; SWIFT/BIC BTACPAPA; RUC #4199990–1–427208 (Panama) [SDNTK]. Designated for materially assisting in, or providing financial or technological support for or to, or providing goods or services in support of, the international narcotics trafficking activities of the WAKED MONEY LAUNDERING ORGANIZATION, Nidal Ahmed WAKED HATUM, and/or Abdul Mohamed WAKED FARES, and/or being owned, controlled, or directed by, or acting for or on behalf of, Nidal Ahmed WAKED HATUM, Abdul Mohamed WAKED FARES, and/or STRATEGIC INVESTORS GROUP, and therefore meets the criteria for designation pursuant to sections 805(b)(2) and/or (3) of the Kingpin Act, 21 U.S.C. 1904(b)(2) and/or (3).

62. BALBOA SECURITIES, CORP., Edificio Balboa Bank & Trust, Calle 50 y Calle Beatriz Maria Cabal, Panama, Panama; RUC #965431–1–528815 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by STRATEGIC INVESTORS GROUP INC. and/or Nidal Ahmed WAKED HATUM, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

63. GRUPO W S.A. (a.k.a. HOMETEK), Pueblo Nuevo Calle 22 Edificio La Galera Local 8, Panama, Panama; RUC #4067941425327 (Panama) [SDNTK]. Designated for materially assisting in, or providing financial or technological support for or to, or providing goods or services in support of, the international narcotics trafficking activities of the WAKED MONEY LAUNDERING ORGANIZATION and/or Nidal Ahmed WAKED HATUM, and/or being owned, controlled, or directed by, or acting for or on behalf of, Gazy WAKED HATUM, Ali WAKED HATUM, Jalal Ahmed WAKED HATUM, and/or Nidal Ahmed WAKED HATUM, and therefore meets the criteria for designation pursuant to sections 805(b)(2) and/or (3) of the Kingpin Act, 21 U.S.C. 1904(b)(2) and/or (3).

64. GRUPO WISA, S.A. (a.k.a. LA RIVIERA), Calle 15 entre Avenida Santa Isabel y Avenida Roosevelt, Zona Libre de Colon, Colon, Panama; Torre Generali, Piso 11 y 12, Calle 54 Este y Avenida Samuel Lewis, Panama, Panama; Colombia; Guatemala; Belize; Costa Rica; El Salvador; Mexico; Bolivia; Honduras; Nicaragua; Uruguay; RUC #645451–1–458900 (Panama) [SDNTK]. Designated for materially assisting in, or providing financial or technological support for or to, or providing goods or services in support of, the international narcotics trafficking activities of the WAKED MONEY LAUNDERING ORGANIZATION and/or Abdul Mohamed WAKED FARES, and/or being owned, controlled, or directed by Abdul Mohamed WAKED FARES, and therefore meets the criteria for designation pursuant to sections 805(b)(2) and/or (3) of the Kingpin Act, 21 U.S.C. 1904(b)(2) and/or (3).

65. PERSHORE INVESTMENTS S.A., Edificio Balboa Bank & Trust, Calle 50 y Calle Beatriz Maria Cabal, Panama, Panama; RUC #1420780–1–631797 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by STRATEGIC INVESTORS GROUP INC, BALBOA BANK & TRUST, and/or Nidal Ahmed WAKED HATUM, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

66. STRATEGIC INVESTORS GROUP INC. (a.k.a. SI GROUP), Edificio Balboa Bank & Trust, Calle 50 y Calle Beatriz Maria Cabal, Panama, Panama; RUC #1649734–1–675348 (Panama) [SDNTK]. Designated for materially assisting in, or providing financial or technological support for or to, or providing goods or services in support of, the international narcotics trafficking activities of the WAKED MONEY LAUNDERING ORGANIZATION, Nidal Ahmed WAKED HATUM, and/or Abdul Mohamed WAKED FARES, and/or being owned, controlled, or directed by Nidal Ahmed WAKED HATUM and/or Abdul Mohamed WAKED FARES, and therefore meets the criteria for designation pursuant to sections 805(b)(2) and/or (3) of the Kingpin Act, 21 U.S.C. 1904(b)(2) and/or (3).

67. STRATEGIC OIL CORP., Edificio Balboa Bank & Trust, Calle 50 y Calle Beatriz Maria Cabal, Panama, Panama; RUC #2432399–1–809429 (Panama) [SDNTK]. Designated for being owned, controlled, or directed by STRATEGIC INVESTORS GROUP INC. and/or Nidal Ahmed WAKED HATUM, and therefore meets the criteria for designation pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3).

68. VIDA PANAMA (ZONA LIBRE) S.A., Enrique A. Jimenez y Calle 16, Zona Libre de Colon, Colon, Panama; RUC #238590056210046 (Panama) [SDNTK]. Designated for materially assisting in, or providing financial or technological support for or to, or providing goods or services in support of, the international narcotics trafficking activities of the WAKED MONEY LAUNDERING ORGANIZATION and/or Nidal Ahmed WAKED HATUM, and/or being owned, controlled, or directed by Gazy WAKED HATUM, Ali WAKED HATUM, Jalal Ahmed WAKED HATUM, and/or Nidal Ahmed WAKED HATUM, and therefore meets the criteria for designation pursuant to sections 805(b)(2) and/or (3) of the Kingpin Act, 21 U.S.C. 1904(b)(2) and/or (3).

69. WAKED MONEY LAUNDERING ORGANIZATION, Panama [SDNTK]. Designated for playing a significant role in international narcotics trafficking, and therefore meets the criteria for designation pursuant to section 805(b)(4) of the Kingpin Act, 21 U.S.C. 1904(b)(4).

Dated: May 5, 2016.

John E. Smith,

Acting Director, Office of Foreign Assets Control.

[FR Doc. 2016–10944 Filed 5–9–16; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Forms 14417 and 14417–A

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 14417, Reimbursable Agreement—Non-Federal Entities and Form 14417–A, Statistics of Income—User Fee.

DATES: Written comments should be received on or before July 11, 2016 to be assured of consideration.

ADDRESSES: Direct all written comments to Tuawana Pinkston, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the forms and instructions should be directed to Martha R. Brinson, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW., Washington, DC 20224, or through the Internet at *Martha.R.Brinson@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Reimbursable Agreement—Non-Federal Entities and Statistics of Income—User Fee.

OMB Number: 1545–2235.

Forms Number: 14417 and 14417–A.

Abstract: Form 14417, Reimbursable Agreement—Non-Federal Entities, was developed for funds in reimbursable agreements with non-federal entities such as state, local, foreign governments and non-federal public entities. Form 14417–A, Statistics of Income—User Fee, was developed to be used after a customer contacts the Statistics of Income (SOI) Division requesting data not already available on our TaxStats IRS Web site.

Current Actions: There are no changes in the paperwork burden previously approved by OMB. This form is being submitted for renewal purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: State, Local, and Tribal Governments.

Estimated Number of Respondents: 310.

Estimated Time per Respondent: 31 minutes.

Estimated Total Annual Burden Hours: 160.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: May 2, 2016.

Tuawana Pinkston,

IRS Reports Clearance Officer.

[FR Doc. 2016–10856 Filed 5–9–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Settlement Funds.

DATES: Written comments should be received on or July 11, 2016 to be assured of consideration.

ADDRESSES: Direct all written comments to Tuawana Pinkston, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulation should be directed to Martha R. Brinson, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW., Washington, DC 20224, or through the Internet at *Martha.R.Brinson@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Settlement Funds.

OMB Number: 1545–1299.

Regulation Project Number: TD 8459.

Abstract: This final regulation prescribes reporting requirements for settlement funds, which are funds established or approved by a governmental authority to resolve or satisfy certain liabilities, such as those involving tort or breach of contract. The final regulation relates to the tax treatment of transfers to these funds, the taxation of income earned by the funds, and the tax treatment of distributions made by the funds.

Current Actions: There is no change in the paperwork burden previously approved by OMB.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals, business or other for-profit organizations, not for-profit institutions, farms and Federal, state, local or tribal governments.

Estimated Number of Respondents: 1,500.

Estimated Time per Respondent: 2 hrs., 22 min.

Estimated Total Annual Burden Hours: 3,542.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: May 2, 2016.

Tuawana Pinkston,

IRS Reports Clearance Officer.

[FR Doc. 2016–10854 Filed 5–9–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

Enhanced-Use Lease of the Department of Veterans Affairs Real Property for the Continued Management, Maintenance, and Operation of a Mixed-Use Development, Including an Office Building, on a Parcel of Land Totaling Approximately 15 Acres in Columbia, South Carolina

AGENCY: Department of Veterans Affairs

ACTION: Amended Notice of Intent to Enter into an Enhanced-Use Lease Amendment

SUMMARY: The Secretary of VA intends to amend the scope and terms of an existing Enhanced Use Lease (EUL) that was entered into on November 19, 2007, for a parcel of approximately 28 acres of land, for the purpose of developing, financing, constructing, managing, maintaining, and operating a mixed-use development. Since that time, the needs of the local VA Medical Center have changed such that VA now requires taking back control of a 13 acre portion of the original parcel included in the EUL in order to renovate an existing historical building, construct additional facilities on the parcel, and obtain parking spaces. This notice provides details on the scope of the amended EUL. The EUL Lessee will continue to manage, maintain, and operate a mixed-use development on 15 acres, including a 137,000 square foot office building. The Lessee will also provide ground lease rent payments to support additional Veteran services.

FOR FURTHER INFORMATION CONTACT: Edward L. Bradley III, Office of Asset Enterprise Management (044), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 461–7778.

SUPPLEMENTARY INFORMATION: As required under Section 211(b)(2)(B) of Public Law 112–154, because the EUL was entered into prior to January 1, 2012, this amended EUL will adhere to the prior version of VA's EUL statute as in effect on August 5, 2011.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Robert A. McDonald, Secretary of Veterans Affairs, approved this document on May 2, 2016, for publication.

Approved: May 2, 2016.

Jeffrey M. Martin,

Office of Regulation Policy and Management, Office of the General Counsel.

[FR Doc. 2016–10858 Filed 5–9–16; 8:45 am]

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Part II

Department of Education

34 CFR Part 200
Title I—Improving the Academic Achievement of the Disadvantaged (Migrant Education Program); Final Rule

DEPARTMENT OF EDUCATION

34 CFR Part 200

RIN 1810–AA99

[Docket ID ED–2013–OESE–0119]

Title I—Improving the Academic Achievement of the Disadvantaged (Migrant Education Program)

AGENCY: Office of Elementary and Secondary Education, Department of Education.

ACTION: Final regulations.

SUMMARY: The Secretary issues regulations to implement the Migrant Student Information Exchange (MSIX), a nationwide, electronic records exchange mechanism mandated under title I, part C, of the Elementary and Secondary Education Act of 1965, as amended (ESEA). As a condition of receiving a grant of funds under the Migrant Education Program (MEP), each State educational agency (SEA) must collect, maintain, and submit minimum educational and health information to MSIX within established time frames. The regulations are designed to facilitate timely school enrollment, grade and course placement, accrual of secondary course credits, and participation in the MEP for migratory children. Additionally, the regulations ultimately will help the Department to determine more accurate migratory child counts and meet other MEP reporting requirements.

DATES: These regulations are effective June 9, 2016. However, affected parties do not have to comply with the information collection requirements in § 200.85 until the Department of Education publishes in the **Federal Register** the control number assigned by the Office of Management and Budget (OMB) to these information collection requirements. Publication of the control number notifies the public that OMB has approved these information collection requirements under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Sarah Martinez, U.S. Department of Education, 400 Maryland Avenue SW., Room 3E343, Washington, DC 20202–6135. Telephone: (202) 260–1334 or by email: *sarah.martinez@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Executive Summary

Purpose of This Regulatory Action: The MEP is a formula grant program authorized under part C of title I of the ESEA. The purpose of the program is to ensure, among other things, that all migratory children have the opportunity to meet the same challenging academic standards that all children are expected to meet, and to prepare them for successful transition to postsecondary education or employment. The purpose of this regulatory action is to update the current MEP regulations in order to fully implement MSIX, a Web-based platform established and maintained by the Department that links States' migrant student record systems to facilitate the national exchange of educational and health information for migratory children. These regulations are necessary for the Department to effectively implement the requirement in section 1308(b) of the ESEA that the Secretary ensure the linkage of migrant student record systems and for the effective implementation of the MEP by States and local operating agencies (LOAs) serving migratory children. In addition, section 1304(b)(3) of the ESEA requires SEAs to provide for educational continuity through the timely transfer of pertinent school records, including information on health, when children move from one school to another, whether or not such move occurs during the regular school year. Thus, this congressionally mandated records transfer system will help SEAs, local educational agencies (LEAs), and LOAs meet the needs of migratory children by having complete, accurate, and up-to-date educational and health information immediately available to school and program staff where migratory children enroll after they move. As defined in section 1309(1) of the ESEA, an LOA is a recipient of MEP funds, which may be an LEA to which an SEA makes an MEP subgrant, or a public or private agency with which an SEA or the Secretary makes an arrangement to carry out an MEP project. A more complete background on migratory children and their unique needs as they relate to records transfer may be found in the *Background* section.

Summary of the Major Provisions of This Regulatory Action: Until now, all but one State receiving MEP funds have voluntarily entered some minimum data elements (MDEs) into MSIX. However, there is not consistency in the timeframes within which States enter these data, or in the completeness of data that each State enters for its migratory children. These regulations establish basic standards governing the collection of MDEs that States receiving MEP funds will need to submit to MSIX, so that when migratory children move and enroll in new schools and programs, staff in those schools and programs may make timely and appropriate decisions to facilitate school enrollment, grade and course placement, accrual of secondary course credits, and participation in the MEP.

For purposes of start-up submissions, an SEA must submit all MDEs applicable to a migratory child's age[1] and grade level (*i.e.,* "applicable MDEs") within 90 calendar days of the effective date of these regulations for all migratory children who are eligible to receive MEP services in the State on the effective date of the regulations, other than through continuation of services provided under section 1304(e) of the ESEA. In addition, after the effective date of the regulations, SEAs must adhere to specific timeframes to collect and submit to MSIX the applicable MDEs for: Migratory children for whom an SEA has approved a new Certificate of Eligibility (COE), end of term submissions, and change of residence submissions. The timelines required for these subsequent data submissions range from four working days to 30 calendar days. The regulations also require that SEAs establish procedures, develop and disseminate guidance, and provide training in the use of MSIX Consolidated Student Records. SEAs must also use, and require their LOAs to use, reasonable methods to ensure data quality and data protection. Finally, the regulations contain specific requirements for responding to MSIX record correction requests from parents, guardians, and migratory children. A more detailed discussion of the major provisions of this regulatory action may be found in the *Analysis of Comments and Changes* section of this preamble.

Costs and Benefits: We have estimated the cost and burden associated with these regulations based on data from MSIX, Consolidated State Performance Reports (CSPRs), and the U.S. Bureau of Labor Statistics National Compensation Survey: Occupational Earnings in the United States. We estimate that the total cost to participating SEAs of implementing these regulations is approximately $17,363,639 for the first year, and $16,431,718 annually thereafter. The estimated burden per migratory child, amortized over three years, is approximately one hour and 30 minutes, at an approximate cost of $46.50 per year. These estimates cover the costs of all requirements in these regulations, including the costs of information collection activities, which are discussed separately under the heading *Paperwork Reduction Act of 1995*. Estimates are based on the initial three-year period for which we anticipate OMB will approve the information collection associated with these regulations.

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[1] So that their children have ready access to school programs, migratory parents may present to LEAs a variety of documentation to prove that their children fall within state- or district-mandated minimum and maximum age requirements. The kinds of documents LEAs generally accept include a religious, hospital, or physician's certificate showing date of birth; an entry in a family bible; an adoption record; an affidavit from a parent; a birth certificate; or previously verified school records.

The requirement that agencies serving migratory children use MSIX and the Consolidated Student Records generated by MSIX will ensure not only that information in MSIX is used, but also that States and LOAs acquire an interest in ensuring the quality and timeliness of the data they provide to and obtain from the system. Other benefits include access to Consolidated Student Records that are current, accurate, complete, and secure, and that contain data that may be currently maintained in different systems within States; for example, State assessment data may not be maintained in the same system as student health records. States' previously voluntary participation in MSIX reflects the value they see in having this information on migratory children in one centralized location, which enables them to better serve one of their most vulnerable populations.

For these reasons, the Department believes that the benefits of these regulations will significantly outweigh the estimated costs, much of which will be met with Federal resources. A more detailed discussion of the costs and benefits of these regulations may be found in the *Regulatory Impact Analysis* section of this preamble.

Background

A "migratory child" is defined by section 1309(2) of the ESEA, as amended by the No Child Left Behind Act (NCLB),[2] and 34 CFR 200.81 as a child who is, or whose parent or spouse is, a migratory agricultural worker or migratory fisher; and who has moved within the preceding 36 months in order to obtain, or to accompany such parent or spouse in order to obtain, seasonal or temporary employment in agriculture or fishing work. In addition, the definition of "child" in 34 CFR 200.103(a), unchanged by ESSA, further requires a migratory child to be not older than age 21 and be entitled to a free public education through grade 12, or be below the age and grade level at which the LEA provides a free public education. Under the MEP, each SEA is responsible for: (1) Determining whether a child meets this definition of a migratory child, and (2) documenting this information on a COE established by the Secretary (and maintaining any additional documentation needed to confirm that the child meets this definition of a migratory child (see 34 CFR 200.89(c)). In this document, when we refer to a child "eligible for the MEP" or an "MEP-eligible" child, we mean that a State has determined that the child meets the programmatic definition of a migratory child, and has documented the child's eligibility for the MEP on a COE. Participation in the MEP is voluntary, and a migratory parent or guardian (or in the case of emancipated youth, migratory children themselves) may choose not to participate in the MEP, in which case they will not be eligible to receive MEP services or be included in the State's count of migratory children. A guardian is defined in Chapter II, Section B of the MEP Non-Regulatory Guidance as any person who stands in the place of the child's parent ("in loco parentis"), whether by voluntarily accepting responsibility for the child's welfare or by a court order, and a legal document establishing guardianship is not necessary to establish an individual as the child's guardian for purposes of the MEP. We apply the same definition to the term "guardian" used throughout these regulations.

The educational needs of migratory children present unique challenges for educators and our Nation's schools. Given the nature of their employment, migratory workers and their families often settle in a single community for a short period of time. One consequence of this mobile lifestyle is that migratory children frequently enroll in new schools and school districts without adequate, and in many cases any, documentation of their educational and health history. School staff at all levels need basic enrollment data, and typically proof of immunizations, to place students in the correct grade or course in a timely manner. Migrant educators have stressed that students in secondary grades have the greatest need for the timely exchange of records because they have limited time to correct mistakes that school officials make if they lack information needed for proper grade placement, course selection, and accrual of course credits required for high school graduation. Because migratory children may move at any time, including during the summer term when many schools are closed, it is imperative to have a reliable system with which SEA, LEA, and LOA staff may access up-to-date educational and health information for migratory children in a timely manner. MEPs operate throughout the year, including during the summer; having timely access to a migratory child's educational and health information will help ensure that MEPs can provide migratory children with services that appropriately address their unique needs.

MSIX helps meet the needs of migratory children by making current educational and health information on those children immediately available to school and program staff where migratory children enroll after they move. MSIX allows SEAs to upload the required MDEs from their own existing State student record systems into a single data repository where information on each migratory child is maintained, organized, and compiled. As a Web-based platform, MSIX allows authorized users to access a migratory child's MSIX record via a Web browser. Specifically, from the MDEs that States collect and maintain on each migratory child in their own State student record systems and that are uploaded into the system, MSIX generates a "Consolidated Student Record." This Consolidated Student Record compiles educational and health-related MDEs from the various schools and migrant education programs in which a migratory child has enrolled, within and across States.

The Consolidated Student Record serves as a starting point to facilitate school enrollment, grade and course placement, credit accrual, and participation in the MEP for migratory children. However, it is not necessarily the sole source of data that educators would use to make these decisions. For example, the Consolidated Student Record does not contain a child's immunization records or Individual Educational Plan (IEP); rather, it will alert the user to whether such records exist and from where they can be obtained. But, as a result of these regulations, a student's essential educational and health information will be presented in a uniform format, and consolidated in a central location from existing record systems within and across States. The necessary information will be available in a timely manner, and the system will direct users to other necessary information from both records in, and outside of, the State.

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[2] On December 10, 2015, the President signed the Every Student Succeeds Act (ESSA), Public Law 114–95, (2015), which amends the Elementary and Secondary Education Act of 1965 (ESEA). The ESSA amends the Migrant Education Program and those amendments take effect on July 1, 2017. Public Law 114–113. Throughout this document we refer to the ESEA when referencing provisions that are included in both NCLB and ESEA. When referencing provisions included under only NCLB, we refer to the "ESEA, as amended by NCLB."

On December 27, 2013, the Secretary published a notice of proposed rulemaking (NPRM) for this program in the **Federal Register** (78 FR 79222). In the preamble of the NPRM, we discussed on pages 79224 through 79230 the major proposals to ensure that basic educational and health records of migratory children are available promptly to facilitate school enrollment, grade and course placement, credit accrual, and participation in the MEP. These final regulations maintain the same basic structure of the major proposals, and thus will require each SEA that receives a grant of MEP funds to—

- Collect, maintain, and submit current and updated MDEs for migratory children to MSIX within established timeframes;
- Ensure that all data submitted to MSIX are accurate and complete and that appropriate safeguards are in place to protect the integrity, security, and confidentiality of Consolidated Student Records in MSIX;
- Establish procedures for using, and requiring each of its subgrantees to use, Consolidated Student Records provided by MSIX; and
- Establish procedures for MSIX data correction by parents, guardians, and migratory children. Additionally, we noted that final regulations will ultimately help the Department to produce national statistical data on the migratory population.

Significant Changes in the Regulations: The following is a summary of the significant changes in these final regulations from the regulations proposed in the NPRM. The rationale for each of these changes is discussed in the *Analysis of Comments and Changes* section of this preamble.

- Section 200.85(b)(1) has been amended to clarify the SEA's responsibility to collect and submit to MSIX the applicable MDEs for all eligible migratory children, regardless of the type of school in which the child is enrolled (*e.g.*, public, private, or home school), or whether a child is enrolled in any school. We also have clarified how the SEA meets its responsibility to collect these records in the case of migratory children who are or were enrolled in private schools or home schools. In addition, we have added specific data collection methods that an SEA must use in seeking to obtain the necessary educational and health information for eligible migratory children who attend, or previously attended, private schools.
- Section 200.85(b)(2) has been amended to limit the data collection requirements for every migratory child whom the SEA considers eligible for the MEP for purposes of start-up data submissions. We had proposed that SEAs be required to collect and submit to MSIX MDEs for every migratory child whom the SEA considered eligible for MEP services (in accordance with 34 CFR 200.89(c)) within one year prior to the effective date of the final regulations. As provided in these final regulations, SEAs must instead collect and submit to MSIX, as their start-up submissions, MDEs for every migratory child whom the SEA considers eligible to receive MEP services in the State on the effective date of these regulations, other than through continuation of services provided under section 1304(e) of the ESEA. Thus, SEAs will not need to go back one year to identify the migratory children for whom they must make start-up submissions. If an SEA has learned that a child whom it had found to be MEP-eligible is no longer eligible for the MEP (*e.g.*, the child is over age 21, is no longer entitled to a free public education through grade 12) or is not residing in the State as of the effective date of these regulations, the SEA does not need to submit to MSIX start-up MDEs for that child.

Because of this change to the requirement for start-up submissions, proposed section 200.85(b)(2)(ii) is no longer applicable. In this subsection, we had proposed requiring SEAs to make start-up submissions to MSIX for a migratory child whom the State considered eligible for MEP services within a year prior to the effective date of these regulations, whether or not the SEA has a current COE for the child at the time the SEA submits the start-up data. Accordingly, proposed section 200.85(b)(2)(ii) has been removed from these final regulations.

- Section 200.85(b)(3)(i) has been amended to replace the term "newly documented migratory children" with "migratory children for whom an SEA has approved a new Certificate of Eligibility." The Department considers the two terms to be synonymous, but has implemented the change for purposes of clarity, based on confusion expressed in comments.
- Section 200.85(b)(3)(ii)(B) has been amended to remove the second sentence of the proposed regulation, which required SEAs to submit MDE updates and newly available MDEs for any child who continues to receive MEP services under section 1304(e) of the ESEA after expiration of MEP eligibility. SEAs will still be required to submit MDE updates and newly available MDEs through the end of the school year for a child whose eligibility expired before the end of the school year, regardless of whether the child continued to receive MEP services under ESEA section 1304(e).

Public Comment: In response to our invitation in the NPRM, more than 300 parties submitted comments on the proposed regulations. We group major issues according to subject. We discuss other substantive issues under the specific section number to which they pertain. Generally, we do not address technical and other minor changes.

Analysis of Comments and Changes

Support for the Proposed Regulations

Comments: Several commenters expressed support for these regulations. Commenters supported the overall intent and purpose of the regulations to meet the unique needs of migratory children. One commenter noted that full implementation of the Migrant Student Information Exchange (MSIX) is long overdue, given that Congress authorized the system in 2001. Commenters also supported specific aspects of the regulations, such as records transfer for secondary students and the reporting activities required under § 200.85(b)(3) for newly documented children, and end of term and change of residence submissions.

Discussion: We appreciate the commenters' support for these regulations.

Changes: None.

Statutory Authority To Use MSIX for the Purposes Stated in the Notice of Proposed Rulemaking (NPRM)

Comments: A number of commenters disputed the Department's authority to use the system for some of the purposes stated in the NPRM, specifically: To provide stakeholders with census data and statistics on the national migratory population; to generate accurate child counts; and to meet other reporting requirements related to the national migratory child population. Commenters asserted that these purposes exceed the Department's authority under section 1308(b) of the Elementary and Secondary Education Act (ESEA), which directs the Department to implement an interstate migrant student exchange system. One commenter stated that broadening the purposes beyond those stated in the statute would violate the Administrative Procedure Act (APA).

In addition, one commenter interpreted the language of section 1308 of the ESEA, as amended by NCLB, which provides that the Secretary shall assist States in developing effective methods for the electronic transfer of student records and in determining the number of migratory children, to mean that while the Secretary is authorized to assist States in these regards, the Secretary is not authorized to require States to use the system, as proposed in the NPRM.

Discussion: The Department appreciates, but disagrees with, these comments.

The Secretary is authorized to use MSIX data for the purpose of providing stakeholders with census data and statistics on the national migratory population and to meet other reporting requirements related to the national migratory child population. In administering the Migrant Education Program (MEP) and other Federal education programs, one of the Secretary's responsibilities is to provide the States, Congress, and the public with the most accurate information possible about the programs and the population they serve so that States, Congress, and the public may use this information to understand the programs and improve program operations. See, for example, section 431 of the Department of Education Organization Act (20 U.S.C. 1231a), which authorizes the Secretary to inform the public about federally supported education programs and collect data and information on applicable programs in order to obtain objective measurements of the effectiveness of those programs in achieving their intended purposes. See also section 4 of the Government Performance and Results Act (GPRA) (31 U.S.C. 1116), which directs each Federal agency annually to report on how well each program has met its established performance targets.

For the MEP, having and reporting the most reliable information available is important not only to support the Department's monitoring efforts and to help States to properly administer their own grant and subgrant programs. It also is important to help inform Congress's appropriations and legislative decisions about the MEP and the results it is achieving. Provided the Secretary is satisfied that the information contained in MSIX is useful for obtaining and reporting these aggregate and non-personally identifiable data, the Secretary is authorized to use MSIX to carry out this duty.

To date, all States that receive MEP funds do so on the basis of the Secretary's approval of consolidated State applications submitted under section 9302 of the ESEA. Under section 9304(a)(6) of the ESEA, in exchange for annual receipt of MEP funds on the basis of a consolidated State plan, each State educational agency (SEA) provides an assurance that the SEA will "(A) make reports to the Secretary as may be necessary to enable the Secretary to perform the Secretary's duties under each such program; and (B) . . . provide such information to the Secretary . . . as the Secretary may find necessary to carry out the Secretary's duties." This assurance mirrors the assurance required in single State applications under section 441(b)(6) of the General Education Provisions Act (20 U.S.C. 1232d(b)(6)). Moreover, regardless of whether each State chooses to seek MEP funding under the Every Student Succeeds Act (ESSA) under a comparable consolidated State application, section 433(b) of the General Education Provisions Act (20 U.S.C. 1231c) and 2 CFR 200.336 provide for comparable State reporting to the Secretary.

Regarding the use of MSIX data to secure reliable State child counts of migratory children, we also note that section 1303 of the ESEA builds State child counts into the State funding formula. In determining each State's MEP award, section 1303(e)(1) of the ESEA directs the Secretary to use data that most accurately reflects each State's migratory child count. While we do not propose immediately to use minimum data elements (MDEs) in MSIX for the purpose of generating migratory child counts, section 1303(e) of the ESEA, as amended by NCLB,[3] authorizes the Department to use MDEs in MSIX for this purpose if State counts generated from MSIX are more accurate than State counts now being submitted by each State in their Consolidated State Performance Reports (CSPRs) via EDFacts or that would be generated by any other source of data. Please see the discussion under *Alternative Methods for Collecting and Reporting Data* for the reasons the Department believes that State migratory child counts generated from MSIX will be more accurate than the migratory child counts that States currently submit via EDFacts.

Thus, the Secretary is authorized to collect data to provide stakeholders with census data and statistics on the national migratory population, to generate accurate migratory child counts, and to meet other reporting requirements related to the national migratory child population. To carry out these duties, the Secretary is generally authorized to collect these data using MSIX if MSIX is a repository of the best available data.

We believe that when MSIX is populated with the MDEs for all States' migratory children, it will contain the Nation's most robust, uniform, and comprehensive educational and health records for migratory children. We further believe MSIX is the most efficient and accurate way to meet the Department's administrative responsibilities discussed here. In addition, we note that, as much of the data required to meet these responsibilities is captured by MDEs, collecting the data through MSIX frees up MEP or other State funds that SEAs would otherwise use to generate reports to the Department. In response to comments that these data gathering and reporting purposes exceed the Department's authority under section 1308(b) of the ESEA, which directs the Department to implement an interstate migrant student exchange system, we also note that section 1308(b) does not proscribe the use of non-personally identifiable data contained in MSIX for purposes other than records transfer. Consequently, section 1308 does not affect the general authority of the Secretary, as described above, to use non-personally identifiable MSIX data for census purposes, reports, and generation of child counts.

Finally, we do not agree with the comment that section 1308 of the ESEA, as amended by NCLB, permits the Secretary only to assist States with developing effective methods for electronic transfer of student records and in determining migratory student child counts, but not to require States to use the system. While section 1308(b)(1) of the ESEA, as amended by NCLB requires the Secretary to assist States in these endeavors, section 1308(b) of the ESEA—the specific authority for MSIX—goes much further. Specifically, section 1308(b)(2)(A) of the ESEA requires the Secretary to "ensure the linkage of migrant student record systems for the purpose of electronically exchanging, among the States, health and educational information regarding all migratory students." This provision requires States to use the system.

Changes: None.

Alternative Methods for Collecting and Reporting Data

Comments: A number of commenters expressed policy or cost concerns regarding the Department's intent to use MSIX to provide stakeholders with census data and statistics on the national migratory child population, to generate accurate child counts, and to meet other reporting requirements related to the national migratory child population.

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[3] Section 1303(f) of the ESEA, as amended by ESSA.

A few commenters cautioned that collecting information via MSIX to generate child counts and to meet other reporting requirements would result in States focusing their MSIX efforts on child count data, overshadowing the records transfer purpose of the system. These commenters cited the failure of the former Migrant Student Records Transfer System (MSRTS) as a basis for their concerns.

Several commenters asserted that use of MSIX would amount to a duplication of effort, since States currently collect this information and report it to the Department through EDFacts, which populates the annual CSPR.

Several commenters provided specific reasons why they believe that State-level data systems and the CSPR are preferable methods for collecting and reporting the information needed for migratory child counts and other reporting requirements. Among the reasons cited by these commenters were the constant fluctuation of data contained in MSIX due to updating of records and the frequency of "near-matches" of migratory children on States' MSIX work lists that must be resolved by States prior to submitting MSIX child count data to the Department. A few commenters cited the Department's current use of the CSPR to collect data from States for the MEP as well as other Federal programs, and questioned why the Department no longer considers this data collection sufficient for the MEP.

Commenters also expressed concerns that migratory child counts collected from MSIX would be a "snapshot" of data—reflecting migratory child counts on a particular day, as opposed to data over a period of time—and thus an arbitrary reflection of States' actual numbers of migratory children, which would then unfairly impact States' MEP allocations. One commenter also expressed concern that out-of-school youth (OSY) would be excluded from the data collected via MSIX.

Discussion: The Department appreciates these comments, but does not agree with them. First, we have carefully considered the lessons learned from the MSRTS, which the Department funded by contract with the Arkansas Department of Education until 1995, when Congress agreed with the Department that it should be terminated because it was too costly and underutilized. State use of MSRTS tended to focus too much on generating child counts based on data States provided to MSRTS after they identified children as eligible for the MEP, and too little on its intended purpose—the collection, transfer, and use of educational and health records on migratory children in making school enrollment, placement, and credit accrual decisions. In part, this may have been a natural consequence of the state of technology at the time; while large mainframe computer and terminal sites existed in each State for inputting and downloading data, the collection and reporting of information relied on a paper-based system that had to get print-out reports from terminal sites to the users. For too many migratory children, MSRTS included few educational records. Where records were present, the system proved too slow and burdensome to be useful to school staff.

MSIX, on the other hand, is a Web-based platform. Building on technological advances over the past 20 years, we have designed MSIX and these regulations to prevent the recurrence of the problems that undermined MSRTS. In particular, the regulations are designed to ensure that MSIX users in schools and other project sites that migratory children attend will have ready access to complete, trustworthy, and up-to-date educational and health records, and that the transfer of those records from State records systems through MSIX and then to authorized users in school and project sites occurs speedily and efficiently.

We agree with commenters that the data reported to MSIX for purposes of generating migratory child counts and to meet reporting requirements must not duplicate data that States currently report annually to the Department in the CSPR via EDFacts. Use of MSIX, in fact, should cure many of the persistent problems we have had with the CSPR submissions, making MSIX a more accurate and reliable source of data available on migratory children.

Our ongoing collaboration with State MEP officials in the MSIX Data Quality Initiative (DQI) and Child Count Reconciliation processes have revealed variation among States in what information they include on migratory children in State-level databases, and how these variations cause inconsistencies in what they report to the Department through the CSPR. The Department asked States to participate in the DQI, the purpose of which is to support States by providing assistance in: Analyzing and assessing the quality and completeness of data in MSIX; identifying common issues causing data inaccuracies; identifying and assessing the root causes of data issues; providing more accurate and complete data on migratory children; and increasing the overall quality of MEP data. The MSIX Child Count Reconciliation process consists of four review rounds, in which States voluntarily participate, in order to assist the Department in understanding the process that each State uses to collect and report its child count to the Department via EDFacts. The goal of the process is to establish an accurate, consistent, unduplicated migratory child count through MSIX. This will allow the Department to produce national data on the migratory population.

Based on the DQI and Child Count Reconciliation processes, we have concluded that the data many States submit to the Department in their CSPRs reflect under- or over-counting of the number of eligible migratory children because of a number of factors, including: (1) Failure to submit unduplicated child counts; (2) failure to include in their child counts eligible migratory children who turn three years of age during the reporting period; (3) inconsistent treatment of children whose MEP eligibility has expired, but whom States still serve under the "continuation of services" provision of the MEP program statute (section 1304(e) of the ESEA); and (4) use of different and inconsistent criteria across States in calculating child counts. We have also noted cases in which States have reported in their CSPRs higher numbers of eligible migratory children enrolled in schools during the State-scheduled State assessment timeframe under title I, part A, than the number of eligible migratory children States reported in the corresponding grade levels.

Utilizing MSIX to generate counts of eligible migratory children will avoid these problems through use of a single and uniform set of MSIX internal procedures for calculating unduplicated State migratory child counts. These procedures involve the application of a "logic rule," which specifies the exact data fields and values that will be queried to generate child counts, including, but not limited to: Qualifying arrival date within 36 months of the beginning of the performance period and eligibility expiration date (used to determine whether a child was eligible for at least one day during the performance period); and enrollment, withdrawal, or residency date during the performance period (used to determine whether a child was resident in the State for at least one day during the performance period). If needed to verify these counts and investigate possible duplication, these MSIX procedures can trace preliminary State child counts back to student-level data—functionality that is not available for data that States submit to the Department in CSPRs via EDFacts. When States have submitted all required MDEs to MSIX, and the Department has determined that these data are complete, our intent is to use MSIX to extract data to generate State migratory child counts instead of, not in addition to, having States submit the corresponding data elements to the Department in their CSPRs. Doing so will reduce, rather than add to or duplicate, the total costs of State reporting.

We agree with the commenters who expressed the importance of resolving "near-matches" in MSIX (*i.e.*, resolving which records of migratory children with similar identifying characteristics belong in a single Consolidated Student Record for one migratory child) prior to generating State migratory child counts. Indeed, one of the benefits of MSIX is its capacity to avoid the creation of duplicate Consolidated Student Records for the same migratory child by generating "work lists" for States to resolve. These work lists provide States with a set of "near matches" (by comparing the MDEs uploaded for a newly identified migratory child with comparable data already in the system). By identifying such "near matches" and adding them to work lists for States to resolve, the system ensures that each migratory child has a single Consolidated Student Record that contains the complete course history, assessment, and other MDEs for that child. In doing so, MSIX is able to produce both a national unduplicated child count and more accurate State unduplicated child counts, neither of which can be achieved by the migratory child counts collected via the CSPR.

While we understand commenters' concerns about the generation of child counts using a "snapshot" of migratory child data for a single day, due to the constant fluctuation of information included in the records MSIX generates, the Department will follow very similar procedures to what States should now have in place to generate their child counts from their State databases for CSPR reporting. Data will be extracted from the system on a single day, but will capture the number of eligible migratory children that were resident in the State for at least one day within the defined performance period (currently defined as the 12-month period September 1 through August 31); it will not be limited to only those migratory children that are eligible and resident in the State on the day that the data is extracted from MSIX.

Thus, MSIX is a significantly improved data source compared to currently available data submitted by States through their CSPRs via EDFacts because MSIX allows for unduplicated national counts of migratory children. Such unduplicated counts (1) are essential to the Department's ability to provide accurate reporting on the national program, (2) would be the most appropriate data for a needs assessment or evaluation of the program on a national level, and (3) will decrease costs to States by eliminating their need to report comparable data in their CSPRs.

Finally, in response to a commenter's concern about the exclusion of OSY from MSIX data collection, these regulations require States to submit MDEs for all eligible migratory children, including secondary school-aged migratory children who are not enrolled in school (*i.e.*, OSY) and pre-school children.

Changes: None.

Privacy Concerns

Comments: One commenter expressed concern that MSIX would be used as a tracking tool, discriminating against minority groups (namely, Hispanics of Mexican descent), based on the Department's plans to use MSIX to provide stakeholders with census data and statistics on the national migratory population, to generate accurate child counts, and to use statistical data from MSIX to help meet reporting requirements. The commenter expressed concerns that requiring input of employment information for the parents of migratory children in MSIX and requiring eligible children to enroll in the program, constitute violations of privacy and Fourth Amendment rights (unwarranted search and seizure of information).

Discussion: The Department appreciates the commenter's concern for our Nation's migratory children and families. The commenter's concerns are understandable, given that in recent years, some States have attempted to use the collection of statistical data on immigrant children—note, not specifically migratory children—in a discriminatory manner. However, we do not intend for MSIX to ever be used in a discriminatory manner, and will make every effort to prevent such a use. The Department's position is consistent with its past support of the United States Department of Justice in challenging aforementioned discriminatory State laws, such as Alabama's H.B. 56, Section 28. We do not agree that these regulations in any way constitute an invasion of privacy or violation of migratory parents' Fourth Amendment rights, and below we explain the safeguards in place to prevent MSIX from being used in a discriminatory manner.

Rather, MSIX is a vital resource that Congress directed the Department to implement in order to help meet the educational needs of migratory children. The Department does not require any parent to enroll a child in the MEP, nor does it require any emancipated youth to enroll on his or her own behalf. Migratory agricultural workers, fishers, and their families are asked to provide the necessary information to determine eligibility for the MEP on a voluntary basis, and this information is collected on the child's Certificate of Eligibility (COE) (OMB Control Number 1810–0662). While some of the information included on a COE is provided to MSIX as MDEs for the child, MDEs do not require the collection of specific employment information of migratory agricultural workers and fishers beyond that collected on the COE and, like the COE itself, do not include race or ethnicity data. Thus providing these data to MSIX does not constitute an invasion of personal privacy or violate any Fourth Amendment safeguards.

The Department takes all precautions to protect the data contained in MSIX, consistent with the very limited uses permitted under the MSIX system of records notice published in the **Federal Register** under the Privacy Act on December 5, 2007 (72 FR 68572). In addition to the safeguards that ensure the physical security of the electronic data, the system limits data access to Department and contract staff on a "need to know" basis and, consistent with MSIX's Rules of Behavior that all States must follow, controls individual State and local users' ability to access records within the system by granting user names and passwords and assigning user roles to individuals that restrict access based on user category.

Finally, we note that § 200.85(f) incorporates important requirements to help ensure that States protect the integrity, security, and confidentiality of migratory children's data in MSIX.

Changes: None.

Consultation With Stakeholders

Comments: Several commenters urged the Department to consult further with stakeholders, including MEP State Directors, prior to finalizing these regulations, regarding the implementation of MSIX, the timelines contained in the proposed regulations, and potential barriers to implementation, such as State statutes or State student information systems. One commenter urged the Department to consult with stakeholders to ensure the accuracy of data collected for MSIX, and the use of such data for decision-making by schools.

Discussion: We appreciate the commenters' suggestions, but do not agree that further consultation is necessary prior to finalizing these regulations. We strongly value the opinions of MEP stakeholders, and understand that their input and support are vital to the successful implementation and continued use of MSIX. Since 2002, we have consulted with SEAs to identify an appropriate set of MDEs along with timelines needed to fulfill the statutory requirements for records exchange established when the ESEA was last reauthorized. The Department proposed the timelines associated with the various data submission requirements based on input from various stakeholders. These stakeholders included, most recently, representatives from eight States that responded to the Department's survey of State officials, as well as staff who have worked on records transfer issues at SEAs. In addition, since the inception of MSIX, the State User Group for Analysis and Recommendation (SUGAR) has provided the Department with valuable information related to the MDEs and timelines, and we will continue to consult with that group and State MEP officials on MSIX-related issues in the future.

In addition to these other forms of consultation, the NPRM provided the formal vehicle required by the APA for receiving and considering feedback from all interested parties, including, but not limited to, MEP State Directors and personnel who work directly with the program. Our responses to specific substantive comments on the proposed regulations, including the timelines, are discussed in the respective sections that follow.

Although we do not believe that further consultation is necessary prior to the finalization of these regulations, we are committed to ongoing consultation with stakeholders on how to continue to improve MSIX, including with regard to data quality and the use of MSIX data by school staff, as the commenter recommended.

Changes: None.

Inclusion in MSIX of MEP-Eligible Children Enrolled in Home Schools and Private Schools

Comments: Many commenters objected to the proposal to include in MSIX the records of migratory children who attend home schools or private schools. Most of these commenters questioned the legal basis for including records of migratory home school and private school students in the MSIX system. Several commenters asserted that, because home schools and private schools are not recipients of Federal funding, they should not be subject to Federal requirements, while others specifically cited the protections afforded to private, religious, and home schools by section 9506 of the ESEA.

Many of the commenters who expressed concerns about the reach of these regulations to include records of migratory home school and private school students asserted that the proposed regulations infringe upon the privacy of these students.

A few commenters expressed concerns about the precedent that these regulations would establish for future data collection on home school students. One commenter expressed concerns that under these regulations, home schooled migratory children are subject to requirements that do not apply to other home schooled children, and recommended that the records of migratory home schooled children should only be required to be provided to MSIX if and when such children enroll in public school.

Discussion: MSIX is a system that collects educational and health information about all eligible migratory children and makes this information quickly available to staff of schools and programs in which migratory children enroll in order to help ensure their school enrollment, grade and course placement, accrual of secondary course credits, and proper participation in the MEP. To date, children whom States identify as MEP-eligible predominantly attend public schools, are not yet at an age to attend school, or are OSY. However, the type of school a migratory child attends—public, private, or home school—has no bearing on MEP eligibility.

Section 1308(b) of the ESEA provides that each SEA must implement the electronic exchange system established by the Secretary (*i.e.,* MSIX) for the purpose of transferring among the States "health and educational information regarding *all* migratory students" (emphasis added). Therefore, the SEA has a responsibility to collect and submit into MSIX this information for all migratory students that the SEA has documented as MEP-eligible, regardless of where (or whether) the students attend school. If parents of migratory children (or in the case of emancipated youth, the children themselves) choose to participate in the MEP, the SEA must seek to include their records in MSIX.

In response to commenters who stated that home schools and private schools should not be subject to these requirements because such schools are not recipients of Federal funds, or because of the protections afforded to private, religious, and home schools by section 9506 of the ESEA, we clarify that these regulations do not impose requirements on such schools. Instead, the regulations impose requirements on SEAs to work with parents or emancipated youth themselves to help them arrange to have the private schools provide the applicable MDEs for MEP-eligible children to the SEA for uploading into MSIX, or to have them obtain these records and then provide them to the SEA so that the SEA can do so.

Although the preamble to the NPRM noted that the data submission requirements would apply to any migratory child whom the SEA considers eligible for the MEP, regardless of whether the child is enrolled in a K–12 public school, or in a private school or home school (78 FR 79225), the proposed regulations did not expressly address these requirements in regard to migratory home school and private school students. Accordingly, we are revising § 200.85(b)(1) to clarify that SEAs must collect and submit to MSIX the applicable MDEs for all eligible migratory children, regardless of the type of school in which the child is enrolled (*e.g.,* public, private, or home school), or whether a child is enrolled in any school.

At the same time, although section 1308(b) of the ESEA creates a clear legal basis for including the records of these students in MSIX, we recognize that SEAs do not exercise the same kind of authority over private and home schools that they exercise over local educational agencies (LEAs) and public schools in their States. Accordingly, we are revising § 200.85(b)(1) to clarify how an SEA would meet its responsibility, with respect to MEP-eligible children who attend private schools or home schools, to secure the MDEs related to school records from LEAs and other LOAs that enroll MEP-eligible children.

We did not intend to suggest that an SEA could or should require a private school or home school to provide these records for uploading into MSIX. We presume that a private school generally would voluntarily provide these records to the SEA, LOA, or the parent (or emancipated youth) if it has received a specific request from a parent or emancipated youth to do so. Parents run the home school, so comparable considerations do not apply to it. We also stress that it has been the Department's long-standing interpretation of the MEP program statute (sections 1301 through 1309 of the ESEA) to permit parents to decline to have their children participate in the MEP. If they decline, the SEA would not have responsibility for submitting MDEs for them into MSIX.

However, if a parent agrees to have his or her child participate in the MEP, an SEA has a responsibility under § 200.89(c) to collect and document the information that supports a child's MEP-eligibility on the COE, and the final regulations clarify each SEA's responsibility to collect, maintain, and upload to MSIX all MDEs applicable to the child's age and grade level.

Accordingly, for migratory students in private schools, § 200.85(b)(1) requires the SEA to do two things. First, the SEA must advise the parent of a migratory child, or the migratory child if the child is emancipated, of the necessity of requesting the child's records from the private school. And second, the SEA must facilitate the parent or emancipated child's efforts to request that the private school provide all necessary information from the child's school records either to the SEA or an LOA for uploading into MSIX, or to the parent or emancipated youth directly for provision to the SEA or LOA for this purpose. After this is done, the SEA or LOA must follow up with the parent, emancipated youth, or private school, as appropriate, to see that the requested records are made available. Doing so will help to ensure that the SEA fulfills its responsibilities with regard to record collection and transfer to MSIX for all MEP-eligible children regardless of the child's place of enrollment, and help ensure that educational and health information for the child will be available promptly upon initial or subsequent school enrollments. We believe this approach is the most reasonable one for having SEAs obtain the necessary educational and health information for migratory children who attend, or attended, private schools and home schools given the differing authority SEAs have over private schools and home schools, as opposed to LEAs and public schools in their States.

If a parent does not want his or her child to participate in the MEP for any reason, neither the school nor the parent (or emancipated youth) must provide the child's information to the SEA, and the SEA has no further responsibility to seek the child's records. Thus MSIX and our regulations do not infringe upon the privacy of any child by compelling this information from private or home schooled students and do not set a precedent for requesting information from those who are not obligated to provide it.

Furthermore, we do not agree with the commenter's recommendation that the records of home schooled migratory children should only be required to be submitted to MSIX if and when such children enroll in public school. One of the primary benefits of MSIX and the Consolidated Student Record for a migratory child is that the record contains a migratory child's educational and health history, which MSIX authorized users utilize to make appropriate decisions about a child's school enrollment, grade and course placement, and credit accrual needs regardless of where in the Nation the migratory child may later seek to enroll. In addition, the Consolidated Student Record may be used to determine the MEP services that will best address a migratory child's needs. Consistent with the purpose of section 1308 of the ESEA, MSIX makes these records available for *all* MEP-eligible children, regardless of the type of school they attend, have attended in the past, or may attend in the future.

Changes: We have revised § 200.85(b)(1). We have clarified in the general MSIX data submission requirements that SEAs must collect and submit to MSIX the applicable MDEs for all eligible migratory children, regardless of the type of school in which the child is enrolled (*e.g.*, public, private, or home school), or whether a child is enrolled in any school. In addition, we have clarified that the SEA meets its responsibilities for collecting MDEs from private schools that migratory children attend or have attended by working with the parent or emancipated youth to provide a written request to the private school that the school either provide these records directly to the parent or emancipated youth or to an LOA or the SEA, for uploading to MSIX. The SEA or its LOA also would have responsibilities for following up with the parent, emancipated child, or private school, as appropriate.

Similarly, we have clarified that the SEA meets its responsibilities for collecting MDEs from home schools that migratory children have attended by requesting this information from the parent or emancipated child, either directly or through an LOA.

Comments: A number of commenters expressed concerns about the cost and burden on home school parents and families and private schools associated with the inclusion in MSIX of data on home school students and private school students.

Discussion: As noted above, these regulations do not require private schools or parents of migratory children (or emancipated children themselves) to do anything involuntarily. We do not believe that § 200.85(b)(1) establishes any significant burden on those who do choose to work to have the MDE information on their children from their private or home schools submitted to MSIX. The minimal burden on private school officials who respond to records requests from parents and emancipated children is accounted for in the time and cost associated with collecting the necessary information for any migratory child—whether the burden is assumed by a public school official, a private school official, or an MEP staff member. Beyond this, we will work with SEAs on best practices for the most efficient and inexpensive ways of providing migratory children's MDEs to MSIX, so that private and home schools may benefit from those practices as well.

Changes: None.

Comments: A few commenters asserted that records transfer via MSIX for migratory students attending home school or private school is not necessary, because the need for records transfer is sufficiently addressed by home school and private school families. One commenter stated that the need is met by State and local laws; another stated that the need is met by parents and teachers; and another stated that the need should be met by parents.

Discussion: We do not agree with the commenters that the need for records transfer for all migratory children, including those migratory children attending home schools and private schools, will be sufficiently addressed in the absence of these regulations. All migratory children, including those who attend private schools or home schools, may move to a new area at any time, and as a result may seek to enroll in a public school or an educational program in their new area. If this occurs, these migratory children should benefit from MSIX in the same way as any other migratory child. Although educational records for some migratory children may be transferred in accordance with State and local laws, or as a result of parental requests, the MSIX system will ensure that records are available for all migratory children in a timely manner.

Changes: None.

Other General Concerns Regarding Regulations

Comments: One commenter asked whether the regulations are a way for the Department to compel the one State that does not currently use MSIX to do so.

Discussion: The Department is issuing these regulations to implement the congressional mandate in section

1308(b) of the ESEA that the Secretary establish a system for linking the various State records systems to ensure that MDEs are available for all migratory children whenever they enroll in a new LEA or MEP-funded program. The Department is not singling out any State; indeed, while nearly all States are now voluntarily participating in MSIX, there is not consistency in States' provision of all applicable MDEs for all migratory children, or how frequently States provide new or updated MDEs to MSIX. These regulations are intended to address these matters, so that whenever and wherever migratory children move, the staff of schools and programs in the new locations have ready access to basic information they need for purposes of timely school enrollment, grade and course placement, credit accrual, and provision of services.

Changes: None.

Comments: One commenter expressed concerns that the regulations focus on K–12 students, and are not designed for the OSY subpopulation of migratory children. The commenter noted that his/her State identifies more migratory OSY than migratory K–12 children, and described various barriers or extra burden associated with collecting the necessary data for migratory OSY. These barriers include the fact that (1) all OSY require separate input of MDEs; (2) OSY who are undocumented lack identification and other documentation; and (3) OSY performing work under an H2A visa stay for limited periods of time before moving again. In addition, the commenter stated that his or her State focuses on serving OSY's immediate needs for the limited period of time they remain in the State, and we assume the commenter is concerned about the diversion of resources from these services to implement MSIX requirements.

Discussion: The Department appreciates the commenter's concerns, but does not agree that the regulations insufficiently address the OSY population. These regulations require data submissions for any migratory child whom the SEA considers eligible for the MEP, including OSY. MSIX is a vital resource for the MEP to help migratory OSY return to school, secure the academic course credits they need to obtain a high school equivalency degree, or obtain other educational and related services.

We interpret the commenter's concern regarding the necessity of inputting OSY information separately to mean that data for OSY is not readily available in the State's school-based data systems (for children enrolled in K–12 schools), and therefore cannot be as easily uploaded from such systems. While collecting and maintaining the necessary MDEs for these OSY migratory children might conceivably be more costly than collecting and maintaining them for other migratory children, this is not necessarily the case. Most of the required MDEs, such as name, date of birth, and qualifying arrival date, apply to all migratory children, and would have been collected on the COE when the SEA determined the child's eligibility for the MEP, so an OSY's lack of identification documents should not impose a burden on SEAs solely based on the necessity of transmitting this data to MSIX. In fact, by completing the COE for OSY, the State has already obtained 20 MDEs that it will submit to MSIX using the same electronic interface with MSIX the State uses for any other migratory child. Some of the other 42 MDEs apply only after a child reaches a certain age or grade level. Moreover, the MDEs pertaining to course history only apply to secondary school records. If OSY have not attended secondary school in the United States, the SEA would not need to submit those MDEs for those OSY because such MDEs would not exist. For OSY who have attended secondary schools in the United States, obtaining MDEs from those secondary schools should be no more difficult or burdensome than it is for in-school migratory youth.

Finally, in response to the concern that OSY performing work under H2A visas stay in one location for a brief period of time, we reassert the importance of inputting MDEs for all eligible migratory children. The most mobile migratory children are especially likely to benefit from the immediate access to records contained in MSIX.

Changes: None.

Minimum Data Elements (§ 200.81)

Comments: Several commenters expressed concerns or provided suggestions regarding the MDEs collected in MSIX. One commenter recommended that the MDEs in MSIX be added to the Common Education Data Standards (CEDS) or be modified to adopt the data definitions in CEDS. The commenter cited the increasing use of CEDS by States (including for other Federal data collections and by vendors) and stated that compliance with the MSIX data collections is complicated by definitions that differ from other Federal data collections, citing course history data as an example.

Two commenters recommended additional MDEs. One commenter suggested that we add a migratory worker's Qualifying Activity as an MDE. One commenter recommended that we collect more specific information on migratory students who are English Language Learners (ELLs), specifically the services, assessments, and accommodations provided to ELL migratory students.

One commenter requested that all 72 MDEs be listed in one document. One commenter requested clarification on the Clock Hours, Grade-to-Date, and Course History MDEs. The commenter specifically asked whether Clock Hours is intended to capture the number of hours the student attended a class (hours enrolled and present for instruction) or the number of hours the student was enrolled (regardless of actual attendance). Citing the variation in State procedures for collecting and reporting data received from LEAs at the end of the school year, the commenter also requested that we clarify the frequency with which SEAs must submit Course History MDEs.

One commenter cited burdens associated with the Designated Graduation School MDE and health-related MDEs. The commenter stated that this information is difficult, if not impossible, for smaller States to complete, given that a majority of their migratory population is present for only a few weeks during the summer. One commenter asked the Department to further consider the practicality of the requirement for States to report partial credit, because many States do not currently collect this information in their student record systems.

Discussion: We appreciate the commenters' suggestions, and will consider implementing some of them following issuance of these regulations. In addition to our responses to the commenters' specific questions and comments regarding MDEs in this discussion, we will also continue to provide technical assistance and guidance following issuance of these regulations, in order to help MSIX users understand the specific requirements of the 72 MDEs. If, after consulting with States, the Department concludes that it is necessary to collect additional MDEs beyond the 72 MDEs associated with these regulations, the Department will, as part of Paperwork Reduction Act-required procedures, seek public comment on additional MDEs via publication of an Information Collection Notice (ICN) in the **Federal Register**.

In response to the comment about either adding MSIX MDEs to CEDS, or modifying MDEs to reflect the data definitions used in CEDS, we first clarify for readers what CEDS is. The CEDS project is a national collaborative effort to develop voluntary, common data standards for a key set of education data elements to streamline the exchange, comparison, and understanding of data within and across early learning through postsecondary and workforce (P–20W). To develop voluntary common standards and to support SEAs in improving data quality, the National Center for Education Statistics in 2009 established a technical working group, now called the CEDS Stakeholder Group, which includes representatives from across the P–20W field. CEDS is not a student records system or a data collection, and adoption of the standards, in whole or in part, is voluntary. We note that, when we compared the MSIX MDEs and CEDS, 72 percent of the MDE and CEDS definitions were identical, very similar, or similar. We will explore the feasibility of aligning existing CEDS definitions with the remaining MDEs that are not currently aligned to CEDS and which are not unique to the migratory child population.

With regard to suggestions that we supplement the existing MDEs, we will consider discussing with migrant education stakeholders the desirability of adding to the existing MDEs such information as Qualifying Activity, and more detailed information regarding migratory children who are ELLs. We note that, as information about ELLs is currently collected, MSIX allows all SEAs to upload the MDEs related to student assessments to the system however the State collects and reports them. For example, if the State collects and reports that a student took the assessment in another language, that information will be uploaded to MSIX and appear in the child's MSIX Consolidated Student Record. While we will consider the commenters' suggestions, we remind readers that the Consolidated Student Record is not intended to capture all educational and health information for a migratory child, and will often refer users to records, such as immunization records and Individualized Education Plans (IEPs), that exist outside of MSIX.

We also note that all 72 MDEs are contained in the "MSIX Minimum Data Elements" document that is housed on MSIX and, as such, available to all MSIX users.

With regard to the Clock Hours MDE, this MDE is intended to capture the number of hours that a student was enrolled in a course prior to withdrawal. As noted on the list of MDEs, the Clock Hours MDE is only applicable to courses that a student enrolled in, but has not completed, or for which no credit has been granted. With regard to the Designated Graduation School MDE, this MDE is only supplied by the State in which the student intends to graduate, which, in the great majority of cases, is not a State serving the student only during the summer months or other brief time period. Therefore, providing data for the Designated Graduation School MDE should not significantly affect small States which, as the commenter noted, have a majority of their migratory population present only during the summer. All MDEs related to course history, which include the Grade-to-Date and Clock Hours MDEs, are currently only applicable to secondary school-aged migratory children, and SEAs must update these MDEs in accordance with the timelines specified in the regulations. For example, SEAs must collect and submit new and updated MDEs for migratory children within 30 calendar days of the end of an LEA's or LOA's fall, spring, summer, or intersession terms.

The only health-related MDEs at this time are Immunization Record Flag and Med Alert Indicator. Neither of the health-related MDEs requires SEAs to collect and submit to MSIX a migratory child's immunization records or detailed health information. Rather, each functions as an alert to authorized users that such records exist outside of MSIX. We believe both of these health-related MDEs are essential pieces of information that will facilitate a migratory child's enrollment in school and access to services that address a child's chronic or acute health issue and, accordingly, require all States, including small ones, to include them in MSIX. Finally, with regard to the recommendation that the Department further consider the practicality of requiring SEAs to collect and report partial credit rather than require use of this MDE at this time, we note that the main obstacles to graduation for secondary school-aged migratory children are credit accrual and placement in coursework linked to high school graduation. The migratory lifestyle poses barriers to migratory children's progression from one grade to the next and accrual of credits toward graduation. Credit-granting alternatives, such as the consolidation of partial coursework, may increase the graduation rate of migratory children. We understand the commenter's concern that the collection of partial coursework is not normally done for the general student population, but this is a unique need for migratory secondary school-aged children due to their migratory lifestyle.

Changes: None.

MSIX State Records System and Data Exchange Requirements as a Condition of Receiving MEP Grant Funds (§ 200.85(a))

Comments: Several commenters expressed concern about the consequences for States that do not comply with these regulations, including the timelines for data submissions. One commenter asked what specific actions the Department would take against SEAs that do not comply with the timeframes that the regulations require. One commenter emphasized the importance of realistic timelines in light of the financial sanctions associated with non-compliance. Another commenter stated that because non-compliance results in a loss of funding, the Department must ensure that the regulations adhere to the standard of reasonableness under the APA. Commenters cited the burdens of the regulations for States with smaller MEP allocations in particular, and cautioned the Department that imposing financial penalties for non-compliance could compound States' frustration or deter States from participating in the MEP.

Discussion: We understand commenters' concerns about the possibility that a State that fails to comply with these regulations would face a loss of MEP funding. However, the full implementation of MSIX is a statutory requirement for all SEAs, and therefore we must condition an SEA's receipt of funds on compliance with these regulations.

But while loss of funding is a potential option wherever a grantee fails to comply with basic program requirements, our goal is to work with all SEAs so that there will be no need for the Department to take this kind of action. We want all SEAs to continue to provide migratory children with the services they need to achieve academically; and to facilitate such academic achievement by having timely access to complete records for purposes of school enrollment, grade and course placement, credit accrual, and participation in the MEP. At the same time, we understand that some States will face implementation challenges, and intend to work with them to resolve how they may be addressed before we would consider establishing special grant conditions or other actions authorized by 2 CFR 200.338. We developed these regulations with an understanding that they must adhere to standards of reasonableness under the APA, and believe that they do adhere to those standards and are realistic.

Changes: None.

MSIX State Records System and Data Exchange Requirements—Effect on Services (§ 200.85(a))

Comments: A number of commenters expressed concerns that the amount of funds and staff time required to comply with the regulations would negatively impact the amount of funds and time staff have available to serve and recruit migratory students. One commenter asked the Department to allocate funds to States specifically for the purposes of fulfilling these regulatory requirements, in order to alleviate the burden on small-allocation States in particular.

Discussion: We appreciate the commenters' concerns, but do not agree that further changes are necessary at this time. Separate from these regulations, every State has a responsibility to promote interstate and intrastate coordination of services for migratory children, including providing for educational continuity through the timely transfer of pertinent school records. All SEAs that currently receive MEP funds submitted consolidated State applications, as allowed under section 9302 of the ESEA. Under section 9304(a), each consolidated State application includes a single set of assurances, applicable to each program for which the application was submitted, that provides that each such program will be administered in accordance with all applicable statutes, regulations, program plans, and applications, a provision that mirrors the applicable regulatory requirement in 34 CFR 76.700. The ESEA-specific program assurances section of the consolidated State application requires that each SEA that submits a consolidated application also provide an assurance that it will comply with all requirements of the ESEA programs included in the consolidated application. Thus, whether or not a State submitted a consolidated State application, section 1304(b)(3) of the ESEA would require the SEA to ensure that the State provides for educational continuity through the timely transfer of pertinent school records. This provision must be read in the context of section 1308(b), which creates a separate responsibility for all SEAs receiving MEP funds to implement reasonable regulatory requirements designed to make electronic data transfer work for all migratory students, regardless of the State in which they reside and enroll in school and MEP programs. We strongly believe that these regulations fulfill this requirement.

As explained in the *Regulatory Impact Analysis* section of this document, we do not believe these regulations create unreasonable costs or burdens on States. For example, these regulations piggyback on States' own systems for maintaining appropriate records for migratory children. Nearly all States already participate voluntarily in MSIX and, to varying degrees, submit the MDEs into MSIX for the migratory children they identify as MEP eligible. Moreover, under these regulations, MDEs needed for MSIX may continue to be collected through existing State student-record systems.

For those States that are not currently utilizing MSIX in the manner and within the timelines required by these regulations, we understand that some adjustments to current practices and procedures will be necessary, and that some States may incur greater costs and burden. In response to the commenter who asked the Department to allocate funds to States specifically for the purposes of fulfilling these regulatory requirements, following consultation with MEP grantees, we will consider the feasibility of providing funds or other resources to do so. Further, as we acknowledged in the NPRM, States may use MEP funds to cover the costs associated with implementing the regulations, albeit with the result that less MEP funding would then be available for direct services.

We believe that, when fully implemented, MSIX will create efficiencies in the provision of services to migratory children by making their records available promptly for purposes of school enrollment, grade and course placement, and credit accrual. Having access to such records will allow MEP staff to better serve students by utilizing their academic history and other information to target services to meet their individual needs. Also, the consistent State use of the MSIX email notification system and various MSIX reports, along with the availability of timely and accurate data in MSIX, will make identification and recruitment efforts more efficient.

We believe that the requirements contained in these regulations represent a careful balance between placing burden on States and other agencies providing services to migratory children, and meeting the need for collecting and maintaining updated accurate information about this mobile population in order to ensure timely transfer of pertinent school records when migratory children move from one school district to another.

Changes: None.

MSIX Data Submission Requirements—General Timelines (§ 200.85(b)(1))

Comments: Six commenters stated that the timelines required by the regulations are unrealistic, burdensome, or unreasonable. One commenter stated that regulatory deadlines that conflict with State deadlines would result in the State's non-compliance with regulatory requirements.

Discussion: We acknowledge the commenters' concerns regarding the timelines required by the regulations, but the commenters did not provide us with sufficient information to consider the merit of their concerns or what alternatives they might recommend. We have responded to comments regarding the burden of these regulations as a whole, in the *Regulatory Impact: Costs and Burden Associated with the Regulations* section. We respond to comments regarding specific timelines required by these regulations, in the following sections: *Start-up Data Submissions (§ 200.85(b)(2)); Subsequent Data Submissions—Migratory Children for Whom an SEA has Approved a New Certificate of Eligibility (§ 200.85(b)(3)(i)); Subsequent Data Submissions—End of Term Submissions (§ 200.85(b)(3)(ii));* and *Subsequent Data Submissions—Change of Residence Submissions (§ 200.85(b)(3)(iii)).*

Changes: None.

Start-up Data Submissions (§ 200.85(b)(2))

Comments: Several commenters expressed concerns about the staffing burden associated with start-up submission requirements: Entering data for children considered eligible in the previous year; entering course history and assessment data for children considered eligible in the previous year; verifying data in the State system and MSIX; and making any necessary changes to current staff responsibilities and provision of additional training. One commenter requested that the Department allocate additional funding to small States for the direct communication of State student data systems and MSIX to alleviate the burden on those States of entering the course history and assessment data of every migratory student in the State's system in the year preceding the effective date of these regulations. Several commenters stated that a longer implementation period is needed.

Discussion: We appreciate the commenters' concerns about the burden associated with start-up submissions. Having considered the matter further, we agree that it would be unnecessarily burdensome to require States to collect and submit to MSIX within 90 days of the effective date of the regulations all applicable MDEs for every migratory child the State considered eligible for MEP services within one year preceding the effective date of the final regulations. Accordingly, we have reduced the burden by requiring States to collect and submit to MSIX within 90 days of the effective date of these regulations all applicable MDEs only for every migratory child who is eligible to receive MEP services in the State on the effective date of these regulations, other than through continuation of services provided under section 1304(e) of the ESEA, as opposed to every migratory child the State considered eligible for MEP services within the previous year. By ensuring that the start-up submissions focus only on children whom States consider to be eligible to receive MEP services in the State on the effective date of the regulations, other than through continuation of services, § 200.85(b)(2) reduces the number of children for whom States must collect and submit applicable MDEs, and consequently reduces the burden on States. Moreover, we believe that if an SEA has good reason to believe a migratory child is no longer residing in the State or no longer meets the MEP eligibility criteria (*e.g.*, the child is over age 21, is no longer entitled to a free public education through grade 12), and thus is not eligible to receive MEP services in the State on the effective date of these regulations, that State should not be responsible for start-up submissions. Thus, a State does not need to go back a year to provide start-up submission, and it also does not need to provide start-up submissions for a migratory child for whom it has information—either through MSIX or other means—that the child is no longer eligible for the MEP or is residing out of State on the effective date of the regulations.

We acknowledge that these start-up submissions may require States to provide extra training and/or adjust staff responsibilities in order to collect and submit the necessary data, but start-up data submissions are a one-time effort. Because the Department has reduced the burden for States by narrowing the population of migratory children for whom start-up submissions must be made, we maintain the requirement that States collect and submit this start-up data within 90 days of the effective date of these regulations. We also will consider, upon consultation with States, the feasibility of providing additional funding and resources to States to assist them in meeting the responsibilities entailed by these new regulatory requirements.

Changes: We have revised the requirements for start-up submissions in § 200.85(b)(2), to require SEAs to collect and submit to MSIX the applicable MDEs for migratory children eligible to receive MEP services in the State on the effective date of the regulations, other than through continuation of services provided under section 1304(e) of the ESEA.

Because of this change to the start-up submissions requirement, proposed § 200.85(b)(2)(ii) is no longer applicable. This subsection included a requirement for SEAs to make start-up submissions to MSIX for a migratory child whether or not the SEA has a current COE for the child at the time the SEA submits the start-up data. Under the revised requirement, an SEA will only be required to make start-up submissions for migratory children the SEA considers eligible for MEP services on the effective date of the regulations (*i.e.*, the child has a current, State-approved COE, is age 21 or younger, is entitled to a free public education through grade 12, and is considered still a resident of the State, and so eligible for MEP services), other than on the basis of continuation of services under section 1304(e) of the ESEA. Accordingly, proposed § 200.85(b)(2)(ii) has been removed entirely.

Subsequent Data Submissions—Migratory Children for Whom an SEA Has Approved a New Certificate of Eligibility (§ 200.85(b)(3)(i))

Comments: Based on the wording used in the NPRM for the proposed requirement ("newly documented migratory children"), one commenter questioned the meaning of the term, and whether the 10-day timeframe for collecting and submitting to MSIX the MDEs for such a migratory child begins with the date the COE is completed, entered in MSIX, or signed by the recruiter. The commenter also cited potential delays with such a timeline due to the processes associated with COE quality control, such as COE approval and COE data entry in State systems.

One commenter stated that MEP staff currently make every effort to ensure timely data submissions, and that the timeframes required by § 200.85(b)(3)(i) are unrealistic and will sacrifice data quality for the sake of rapid data entry. One commenter stated that the 10-day timeframe is unrealistic for a small State, as approximately 55 percent of COEs are collected within a three-week timeframe.

Several commenters stated that the 10-day timeframe required under § 200.85(b)(3)(i)(B)(*1*) (for collection and submission to MSIX MDEs from the most recent secondary school in that State attended previously by a newly documented secondary school-aged migratory child) is unreasonable and unnecessary. Commenters cited the following barriers to obtaining the necessary secondary school records within 10 working days: Some MEP summer projects are not affiliated with school districts and do not have direct access to the State data system to obtain the necessary school records; the SEA does not have immediate access to the necessary records at the State level; the SEA relies on LEA staff, who may not be familiar with the MEP, may have competing work priorities, or may be unavailable during summer months; assessment data and other school records are uploaded to the State database on a timeline that does not align with the 10-day requirement contained in the regulations; and lack of staff.

Several commenters provided descriptions of existing State processes for obtaining academic records, as support for why § 200.85(b)(3)(i)(B)(*1*) is unnecessary. The commenters stated that LEAs obtain necessary course history information from the State's own database, and would not rely on, or accept as an authoritative source of information, MSIX records containing secondary course information, for purposes of course placement or credit accrual.

Discussion: In response to the commenter who requested that we clarify both the term "newly documented migratory children" and thereby when the 10-working day requirement begins, we note that: § 200.85(b)(3)(i)(A) states that it begins with the documentation of child's eligibility; and § 200.89(c)(1) provides that the State must use a COE to document eligibility. Therefore, the 10-day period begins with the date the SEA-designated reviewer approves the child's COE. Accordingly, an SEA's quality control processes and procedures associated with reviewing and approving COEs before the SEA-designated reviewer approves the COE does not impact when the 10-day period begins. In addition, given both the confusion expressed in those comments about the meaning of the term "newly documented", and the fact that the Department has not to date used the term "newly documented" to describe migratory children, we have substituted the term used in the NPRM with what we believe is a clearer and synonymous phrase: "migratory children for whom an SEA has approved a new Certificate of Eligibility."

We disagree with the commenters who stated that the 10-working day requirement for subsequent data submissions for migratory children for whom an SEA has approved a new COE is unrealistic or not feasible. As detailed in the Department's 2004 Report to Congress on the "Maintenance and Transfer of Health and Educational Information for Migrant Students by States," the Department engaged in many State consultations in which it received advice on the MDEs and associated timelines. A consensus was reached during the Department's MSIX consultations with SEAs and stakeholders that an SEA could be expected to submit a migratory child's MDEs to MSIX within 10 working days of the date that the SEA documents under § 200.89(c)(1) that the child is eligible for the program. We acknowledge that this requirement and others contained in these regulations may require SEAs to implement changes, such as modifying existing staff responsibilities, providing additional training, or coordinating with non-MEP LEA and/or SEA staff, to ensure the necessary student data can be collected and submitted to MSIX in adherence to the regulatory timelines.

As stated in the paragraph above, the 10-working day requirement starts with the date that the SEA-designated reviewer has approved the child's COE. There is no regulatory requirement for the SEA to identify and recruit a migratory child within a maximum number of days after the child has made a qualifying move; nor is there a regulatory requirement for the SEA to complete the COE approval process within a maximum number of days after the child has been identified and recruited. While we strongly encourage all SEAs to complete these processes and procedures in a timely manner so that migratory children may begin receiving services as quickly as possible, MEP requirements do not dictate when the SEA must complete them or how soon the SEA must begin providing services after the child makes a qualifying move. Still, because migratory children may seek enrollment in school or in an MEP program at any time, we believe it is of critical importance that SEAs collect and submit the applicable MDEs to MSIX for each migratory child for whom an SEA has approved a new COE within no more than 10 working days after the SEA has approved the COE, in order to meet the system's purposes of timely school enrollment, grade and course placement, credit accrual, and participation in the MEP.

We also believe it is reasonable to expect that, for non-secondary school-aged children, a majority of the MDEs applicable to the child's age and grade level will already be available to the SEA; these MDEs would have been collected and recorded on the child's COE. We emphasize that for non-secondary school-aged children, the regulations do not require SEAs to collect and submit MDEs in existence prior to the date that the SEA documents the child's eligibility (*i.e.*, the date that the SEA approved the child's current COE). Collecting and submitting them might well be desirable, but these actions are not covered by the regulations.

For secondary school-aged migratory children, we believe it is necessary for SEAs to collect and submit to MSIX within 10 working days all applicable MDEs from the most recent secondary school in the State previously attended by the child. If the LEA has not already entered the necessary information in the State's database, the SEA will need to collect the necessary information from the school's or LEA's records, and submit it to MSIX within 10 working days of approving a new COE for the migratory child. We understand the commenter's concern that MEP summer projects (LOAs) may not be affiliated with school districts and therefore would not have direct access to the State data system to obtain the necessary school records. However, these regulations apply to the SEA as the Department's grantee; therefore, it is the responsibility of the SEA to ensure that the applicable MDEs for each eligible migratory child are uploaded to MSIX within 10 working days. Meeting this responsibility may entail SEAs amending their current database access policies or procedures to allow MEP summer projects that are not affiliated with a school district to access the State's student database, or ensuring that non-MEP funded LEAs will be available in the summer months to provide the necessary data. The Department plans to issue non-regulatory guidance to assist States in determining the applicable MDEs for secondary school-aged migratory children that must be collected and submitted under this requirement.

We do not agree with the commenters who stated that proposed § 200.85(b)(3)(i)(B)(*1*) is unnecessary, given existing State processes for obtaining academic records. We understand that LEAs likely will not rely on a child's MSIX record as the sole source of information for course placement and credit accrual. However, we do not believe this negates the need for SEAs to collect and submit the applicable MDEs to MSIX within 10 working days of approving a new COE for a secondary school-aged migratory child. Rather, we believe it is essential to have available, within 10 working days of approving a new COE for a migratory child, the minimum data necessary to enroll the child in school and place him or her in the appropriate classes.

Changes: Section 200.85(b)(3)(i) has been amended to replace the term "newly documented migratory children" with the phrase "migratory children for whom an SEA has approved a new Certificate of Eligibility".

Comments: Several commenters expressed concerns with § 200.85(b)(3)(i)(B)(*2*), which requires SEAs to notify MSIX within 30 calendar days of documenting a newly eligible secondary school-aged migratory child if one of its LOAs has obtained records from a secondary school in another State attended previously by the newly documented migratory child. The commenters stated that 30 calendar days is not sufficient time for a small State with minimal staff; the information is difficult or impossible to obtain; there is extra burden imposed on LOAs by the collection of this information; and more time is required to implement the new MDE associated with the proposed requirement (MDE 72, Out-of-State Records Flag), including to acclimate staff. One commenter observed that the new MDE had not been the subject of consultation with the SUGAR group (of which the commenter is a member).

Several commenters asked clarifying questions regarding the new MDE: whether the notification to MSIX must be made by the State or by the district; clarification on the term "notify" and how such notification would impact procedures for transmitting data to MSIX; whether the MDE would consist of a simple check box to indicate that records from a previously attended school had been received; whether information regarding the enrollment record and school must be included; and how the MDE would benefit most secondary students, as subsequent schools may still have to call the original school to request records. One commenter also asked how the Department expects SEAs to monitor and enforce LOA compliance with the requirement to indicate in MSIX whether the LOA has obtained out-of-State secondary school records for a newly documented migratory child.

Discussion: In response to commenters' concerns about § 200.85(b)(3)(i)(B)(*2*), we clarify that these regulations do not require SEAs to seek or obtain the out-of-State records from a secondary school attended previously by the secondary school-aged migratory child for whom an SEA has approved a new COE. If the SEA (or one of its LOAs) does choose to seek and obtain such out-of-State records for a secondary school-aged migratory child for whom the SEA has approved a new COE, the regulations require the SEA to notify MSIX that one of its LOAs has obtained such records within 30 calendar days of receipt of such records; but the regulations do not require the SEA or its LOAs to submit to MSIX the MDEs associated with those out-of-State secondary school records. The timeline of 30 calendar days is based on the Department's survey of eight State officials, in which we asked how many minutes it would take to research whether an out-of-State transcript is present and then indicate in the State's system whether the information is present. Because the regulations do not require SEAs or LOAs to upload the out-of-State records to MSIX, but simply indicate whether an LOA has the records, we believe 30 calendar days is a reasonable timeline.

The new MDE associated with this requirement is a flag that notifies an authorized user of MSIX viewing the child's record that one of a State's LOAs has obtained out-of-State secondary school records for the migratory child for whom an SEA has approved a new COE. When the MDE is fully functional, this will enable another authorized user to go directly to that LOA for the records rather than initiate a second contact with the out-of-State secondary school previously attended by the child. This notification in MSIX may be initiated by LOA or SEA staff, depending on how the SEA chooses to delegate this responsibility. We expect SEAs to monitor compliance with this requirement to the same extent that they are expected to monitor all other MEP programmatic requirements, and we will provide technical assistance and guidance to all SEAs in implementing this new MDE.

Finally, in response to the commenter who noted that this new MDE was not the subject of consultation with the SUGAR group, we note that while the Department values the input of this particular group, we are not required to consult with one specific group of individuals on all MSIX-related matters, including specific MDEs. The NPRM's invitation for public comment is a form of consultation, inviting feedback on all aspects of these regulations, including the new MDE, from all interested parties. We further note that the burden estimates associated with this MDE are based on information provided by the eight States that responded in March 2012 to the Department's survey of State officials. We believe the estimates are reasonable, and do not believe MDE 72 adds a significant additional burden to the overall burden associated with the currently approved MDEs and these regulations. A more detailed discussion of the costs and benefits of these regulations is included in the *Regulatory Impact Analysis* section.

Changes: None.

Subsequent Data Submissions—End of Term Submissions (§ 200.85(b)(3)(ii))

Comments: None.

Discussion: Based on its review of other public comments, the Department reevaluated proposed § 200.85(b)(3)(ii)(B), which addresses the submission of MDEs at the end of each term for migratory children whose eligibility for the MEP expires during the school year. We have determined that the proposed requirement for SEAs to submit MDE updates and newly available MDEs for any child who continues to receive MEP services under section 1304(e) of the ESEA (Continuation of Services) after expiration of MEP eligibility, would place an unnecessary burden on SEAs to collect and submit this information to MSIX.

Depending on how an SEA chooses to implement the discretionary authority in section 1304(e), some formerly eligible migratory children may continue to receive services for one additional school year after expiration of MEP eligibility, and may continue to receive credit accrual services from the MEP through graduation. We did not intend for SEAs to be required, as part of their end of term submissions, to collect and submit data for all formerly eligible migratory children who continue to receive MEP services, beyond the end of the school year in which their MEP eligibility expired. Therefore, we have removed from § 200.85(b)(3)(ii)(B) the proposed requirement that SEAs submit MDE updates and newly available MDEs for all children who continue to receive MEP services under section 1304(e) of the ESEA. We continue to believe that migratory children whose eligibility expires during the school year are best served by having an MSIX Consolidated Student Record that contains the child's educational and health information through the end of the school year. SEAs will be required to collect and submit MDEs through the end of the school year in which the migratory child's eligibility expired, but whether the child continues to receive MEP services under section 1304(e) is not relevant under this requirement.

Changes: We have revised § 200.85(b)(3)(ii)(B) to remove the requirement for SEAs to submit all MDE updates and newly available MDEs for any child who continues to receive MEP services under section 1304(e) of the ESEA after expiration of MEP eligibility.

Comments: Several commenters stated that SEAs might not be able to submit end of term data within 30 calendar days from the end of each term (fall, spring, summer, and intersession terms). They cited barriers such as: Lack of personnel; LEA staff not being present to supply the necessary data during school breaks, or being busy with processing student enrollment and withdrawals from their facilities; and SEAs' inability to access student data from State student databases, due to lack of direct access for MEP staff at the LOA or State level or existing State-mandated timelines for LEAs to submit data to the State system, and State data validation processes.

Several commenters also stated that assessment data would be particularly difficult for SEAs to collect and submit to MSIX within 30 calendar days of the end of each term. Commenters noted that the data might not be available even to LEAs within 30 days of the end of the term because the data is reported and uploaded during the summer months. Also, many LEAs aggregate testing and other data on a variety of timelines, some set by State requirements, others by local school district policies and procedures. One commenter stated that assessment data are not available in the State data system until a year or more after the test is administered.

Discussion: We understand that in some locations this requirement may require changes to long-standing practices and procedures. For example, it may require some SEAs to modify existing staff responsibilities and better coordinate with non-MEP LEA and SEA staff to ensure the necessary student data can be collected and submitted to MSIX in adherence with the regulatory timelines. However, we do not believe those challenges warrant an extension of the 30-calendar day period because any further extension could have a detrimental impact on the ability of local school and MEP staff to have timely access to necessary educational and health records of migratory children. For example, because the summer term is an opportunity to make up for educational interruptions that occur due to the migratory lifestyle, it is imperative that MEP and other staff have access to a migratory child's educational and health information, including assessment data, as soon as possible after the end of the regular school year so that they can determine the summer services that will best address the child's needs.

The regulations do not require that all LEAs upload student data more frequently to the State's student database. LOAs that are not LEAs, or LOAs that do not otherwise have direct access to the necessary data, may collect the necessary data directly from LEAs, and submit the data to MSIX through another records system (such as a State migrant-specific database), if such a process would be more efficient or practicable for an SEA to meet the regulatory requirement. We will provide technical assistance to SEAs and share strategies that have worked in some States that have overcome similar barriers to providing migratory student data to MSIX.

In response to the commenters who expressed particular concern that LEAs would not have student assessment data within 30 calendar days of the end of the term, we intend updated and "newly available" MDEs to mean that the information has been processed by an LEA, LOA, or other responsible party, such as a contractor for the SEA, and could be collected by an SEA (or, as applicable, one of its LOAs). We cannot reasonably expect the SEA to collect and submit MDEs for data that are still being processed, or that are not otherwise accessible to an LEA. We note that under separate, existing requirements for title I, part A, SEAs must ensure that the results of State academic assessments are available to LEAs before the beginning of the next school year (see section 1116(a)(2) of the ESEA, as amended by NCLB).

Changes: None.

Subsequent Data Submissions—Change of Residence Submissions (§ 200.85(b)(3)(iii))

Comments: Some commenters interpreted § 200.85(b)(3)(iii) to require submission of MDEs for a migratory child four days after the COE completion date or after the child becomes eligible for MEP services. One commenter asked whether the notification referenced in the regulations is the same as the move notification in MSIX currently utilized by some MSIX users to alert another school district or State to which the child has moved or will move, and one commenter described challenges posed by that MSIX notification system due to insufficient information provided to the district or State to which the child has moved or will be moving. One commenter interpreted the change of residence notification to require an SEA, within four working days to: Locate the child, complete a COE, approve the COE, and submit the applicable MDEs to MSIX.

Several commenters cited as challenges to compliance with the four-working-day requirement a lack of staff capacity and difficulty in obtaining the necessary data from school districts—either because LEAs are not staffed in the summer months, or because of the time required for school personnel to collect and deliver the necessary information to the regional offices to enter in the State database and upload to MSIX. Two commenters asked the Department to consider extending the four-working-day requirement to 10 days, 15 days, or 14–21 days (14–21 days would align with the current recommended timelines for SEAs to resolve items on their MSIX work lists).

Discussion: We appreciate the commenters' concerns, but do not agree that they warrant a change to the regulatory requirement. In response to the commenters' questions and requests for clarification, we clarify here the differences in data submission requirements under § 200.85(b)(3)(i) for migratory children for whom an SEA has approved a new COE, and the data submission requirements under § 200.85(b)(3)(iii) for migratory children who were previously documented as eligible and have changed residence.

Under § 200.85(b)(3)(i), if an SEA documents a child as newly eligible for the MEP (*i.e.,* the SEA approves a new COE for a child based on a qualifying move, regardless of whether the SEA has previously approved a COE for the same child based on a previous qualifying move), the SEA has 10 working days from the date the SEA-designated reviewer approves the child's COE to submit all applicable MDEs for the migratory child for whom an SEA has approved a new COE. For children whom an SEA previously documented as eligible for the MEP, and for whom the SEA has previously submitted data to MSIX, § 200.85(b)(3)(iii) requires an SEA to submit to MSIX any MDE updates or newly available MDEs for the migratory child within four working days, only if the SEA has received notification from MSIX that the child has changed residence to another LOA within the same State or another SEA has approved a new COE for the child. For example, if a child moves from State A to State B, an MSIX user in State B may initiate a move notification in MSIX, to request the child's educational and health information from State A. Within four working days of receiving such a notification in MSIX, State A must upload to MSIX any updated or newly available MDEs for the child since State A's last submission of MDEs for the child. These regulations do not require State B to initiate the move notification in MSIX. The regulations retain the current flexibility for MSIX authorized users to send a move notification through MSIX to the child's former location, upon determining that the child's record is missing data.

When an SEA receives this type of change-of-residence notification from MSIX, the SEA should understand that the notification is an indication that the child has already left the district or State, not that the child is coming. So, under this regulatory requirement, upon receiving notification that the child has changed residence, the SEA does not need to locate the child in order to collect needed information. Rather, that SEA must submit to MSIX any updates or newly available MDEs that have become available to the SEA or one of its LOAs since the SEA's last submission to MSIX for that child. Under § 200.85(b)(iii)(B), if there is no new or updated MDE information to submit at the time that the SEA receives the change of residence notification, the SEA must enter any new or updated information within four working days of when the data does become available to the SEA or one of its LOAs. Consistent with the discussion in the *Subsequent Data Submissions—End of Term Submissions (§ 200.85(b)(3)(ii))* section, we intend "newly available" MDEs to mean that the information has been processed by an LEA, LOA, or other responsible party, such as a contractor for the SEA, and could be collected by an SEA (or one of its LOAs, should the SEA designate this responsibility to its LOAs).

Some commenters referenced a different type of MSIX notification that many MSIX users currently use on a voluntary, as-needed basis. This is a notification to alert a receiving school district that a migratory child has recently moved to the school district, or will be arriving soon. While we encourage use of this notification, at this time there is no regulatory requirement for SEAs to initiate such advance notifications, nor is there a required timeframe in which SEAs that receive such notifications must locate a child in the new school district to which the child has moved.

We understand that to meet these requirements, some SEAs may need to modify staff responsibilities, processes, and procedures to obtain and submit the necessary data within the required timeline. While we recognize that four working days is a very short timeframe, MEP and school personnel in the migratory child's new State or school district need critical information on the child as soon as possible so that they can make appropriate decisions regarding school enrollment, grade and course placement, accrual of secondary credits, and participation in MEP services. The requirement to obtain and submit data within four working days was informed by the estimates of time needed for data collection, as provided by the group of eight States that responded to the Department's survey of State officials. It is essential to keep the short timeframe because there is no way to know how many days have lapsed between the child's arrival in the new school district and the district's initiation of the change of residence notification in MSIX.

Changes: None.

Use of Consolidated Student Records (§ 200.85(c))

Comments: One commenter asked the Department to specify in the final rule that the Consolidated Student Record (referred to in the NPRM as Consolidated Migrant Student Record) may be used for grade and course placement purposes in conjunction with other local enrollment document review procedures and new student assessment procedures.

One commenter asked the Department to include language in the final regulations that State MEP Directors are to encourage teachers and guidance counselors to use MSIX. The commenter stated that MSIX is not well known by those outside the field of migrant education, including teachers and guidance counselors, and emphasized the importance of these school personnel knowing the benefits of MSIX and being able to use the system, or knowing whom to contact to obtain the necessary information contained in MSIX.

One commenter requested that the Department provide specific expectations for SEAs about how they should monitor compliance with the requirements in § 200.85(c) for use of Consolidated Student Records. One commenter recommended that the Department conduct a periodic evaluation of State manuals, training procedures, and SEA implementation of the requirements under § 200.85(c).

Two commenters expressed concerns about the burden associated with providing MSIX training to school staff, including issuing and updating passwords. One commenter asked the Department to use "unallocated" State funds to establish procedures, develop and disseminate guidance, and provide training in the use of MSIX, to alleviate the burden of these requirements for small States.

Discussion: We appreciate the commenters' concerns, and agree with them in part. We recognize the value of one commenter's approach to grade and course placement for migratory students, which relies on multiple information sources. We fully encourage MSIX users to use a child's Consolidated Student Record in conjunction with other data sources. The Consolidated Student Record is intended to be a starting point for school enrollment, grade and course placement, credit accrual, and participation in the MEP; it is not intended to be relied upon as the sole source of data for a migratory child. For example, the Consolidated Student Record will not contain a migratory child's immunization record but, rather, will alert the MSIX user as to whether such a record exists. Thus, the Consolidated Student Record is intended as a starting point. As a result of these regulations, the information it contains will be available in a timely manner, and will direct users to where they may obtain other pertinent information in intra- and inter-State records.

We agree with the commenter on the value of informing teachers and counselors about, or giving them access to, MSIX. However, we do not agree that it is necessary to specifically require MEP State Directors (or SEAs) to encourage specific personnel as authorized users of MSIX. While we plan to encourage, in subsequent guidance, the use of MSIX by those most likely to utilize the system for its intended purposes, including school teachers and counselors, § 200.85(c)(3) maintains the existing flexibility for SEAs to determine their States' MSIX authorized users. We have developed MSIX training materials specifically designed for MSIX authorized users, and we encourage SEAs to utilize these materials. We will gladly assist SEAs that are interested in developing specific procedures, guidance, and training for their authorized users, including teachers and counselors.

In response to the commenter who asked the Department to provide specific expectations for SEAs regarding monitoring compliance with the regulatory provisions regarding use of the Consolidated Student Record, we do not believe it is appropriate or necessary to include such expectations in these regulations. However, we will provide technical assistance and guidance to assist SEAs with implementation of these regulations and share strategies that SEAs may use to monitor LOAs' compliance. In response to the commenter's recommendation that the Department conduct a periodic evaluation of State manuals, training procedures, and SEA implementation requirements under § 200.85(c), the Department does not currently have plans to evaluate these specific requirements on a national level. We will, however, monitor compliance with these requirements on an as-needed basis, and as part of our standard monitoring procedures. The Department's MSIX contractors also assist with monitoring the implementation of some of the requirements contained in the regulations.

With regard to concerns expressed about the burden associated with MSIX training, we clarify that these regulations do not require all LEAs in the State to use MSIX, nor do these regulations require all LEA staff to be trained as authorized users. The regulations require the SEA and its LOAs to use the system, and require the SEA to encourage its LEAs that do not receive MEP funds (*i.e.,* LEAs that do not meet the definition of an LOA) to use the system. We will provide technical assistance to SEAs to make MSIX training as efficient as possible and share strategies for how SEAs can encourage use of MSIX by LEAs that do not receive MEP funds. We also encourage SEAs to use the materials developed by the Department to minimize the burden on States, including: A template for a State manual to assist States in developing policies and procedures for using MSIX, ensuring data quality, and protecting the data; and online training and a training toolkit for State officials to use in carrying out training within their States. The use of the Department's materials is optional for States, and the templates are meant to be supplemented or adapted by SEAs to incorporate State-specific information.

Finally, we wish to clarify what we understand to be the commenter's reference to "unallocated" State funds: There are no "unallocated" MEP funds. All MEP funds appropriated to the program by Congress are allocated to States or to coordination activities authorized under section 1308 of the ESEA. The Department allocates up to $10 million from the total annual MEP appropriation for coordination activities, of which up to $3 million is allocated for special consortium incentive grants (CIGs) to SEAs. If any of the section 1308 funds allocated for non-CIG coordination activities, such as for the MSIX contract, are unexpended after the end of the initial 15-month period of availability, these unexpended funds are re-allocated to SEAs. If such unexpended funds are re-allocated to SEAs in the form of a supplemental formula award, the SEAs may use the funds for any allowable MEP activity, including implementation of MSIX. As noted in response to other comments, the Department will consult with States to determine the feasibility of, in the future, re-allocating unexpended sections 1308 funds to SEAs in the form of MSIX data quality grants, which must be used for MSIX-related purposes as opposed to general MEP-related purposes.

Changes: None.

MSIX Data Quality (§ 200.85(d))

Comments: One commenter stated that larger States have greater numbers of data entry staff spread throughout the State (*e.g.,* a large State may have 20–30 data specialists working in various locations), and the accuracy of data varies among these locations.

Discussion: We understand that States with greater numbers of data entry staff face greater costs associated with training and measures to ensure consistent data quality for their student records systems. Because the authoritative source of MSIX data is each State's student records systems, the more accurate and complete the data is in such systems, the more accurate and complete the data will be in MSIX. We plan to prepare guidance and offer technical assistance that recommends reasonable and appropriate methods (*e.g.,* running data quality reports in MSIX) that SEAs and their LOAs may use to ensure that all data submitted to MSIX are accurate and complete. While we understand the challenges and increased costs and burden associated with training more staff and monitoring greater amounts of data, we expect all SEAs to implement procedures that ensure that the data uploaded to MSIX are accurate and complete. Setting a lower standard would undermine the purpose of MSIX and negatively impact the intended beneficiaries of the system—migratory children.

Changes: None.

Procedures for MSIX Data Correction by Parents, Guardians, and Migratory Children (§ 200.85(e))

Comments: Several commenters stated that the required timeframes for responses to data correction requests are inadequate or unreasonable, citing a lack of staff and difficulty communicating with migratory parents who commenters state are pre-literate, do not have access to electronic communication, or speak a language in which MEP staff are unable to fluently converse. One commenter asked the Department to advise SEAs on how to communicate the data correction process to such parents and guardians.

One commenter stated that an SEA might not be able to submit the revised data to MSIX within four working days of its decision to revise the data because some of the data transmitted to MSIX may come from other, non-migrant State data systems and must first be revised in those systems—creating a possible need for multiple data transfers. The commenter suggested that the Department revise the requirement to allow an SEA to submit the revised data to MSIX within 10 working days of the data being revised in the State's data system. One commenter stated that SEAs may have difficulty responding within 10 working days to data correction requests received from the Department if such requests are received while districts are closed for holidays or school breaks.

One commenter cautioned about the burden imposed on the SEA by the requirements in § 200.85(e), in terms of tracking and responding to data correction requests, depending on the volume of requests received.

One commenter asked about the process to be followed for data correction requests—specifically, the process for corroborating or validating the record correction request made by a parent, guardian, or migratory child. The commenter also asked whether there would be a process for districts or SEAs to appeal the request. One commenter recommended that the Department provide guidelines to help SEAs design procedures for migratory families to request a correction of MSIX data and that the Department review those State procedures.

Two commenters asked the Department to specify in the final regulations that: SEAs must have easily accessible and translated information for parents, guardians, and migratory children that informs them of the data correction process and how to submit a request, and specifies that a correction request can be made in a language other than English; and the SEA's response must be in an accessible and uniform format that the requestor can understand. One commenter listed several existing Federal laws and policies that protect students and families from discrimination on the basis of national origin, and asked the Department to include specific requirements in the MSIX regulations to clarify that Federal civil rights laws preempt any State and local enactments to the contrary.

Discussion: We understand that the timeframes set forth under these regulations will require changes to current practices and procedures. SEAs are expected to make necessary adjustments to ensure that these requirements are met—for example, modifying staff responsibilities; identifying resources to overcome language or other communication barriers; and ensuring that staff are available to respond to data requests even when school is not in session. We also note that while SEAs and LOAs will need to address difficulties in communicating with parents, they already do so in other MEP contexts, including when conducting the initial interview with the family to determine a child's eligibility for the MEP.

In response to the comment about potential delays between the decision to correct MSIX data and the need first to correct data in other State data systems, as well as the possible need for multiple data transfers, we recognize that the regulations will require efforts on the part of MEP and non-MEP staff at the SEA, LOA, and LEA levels to coordinate and possibly revise existing data correction procedures that apply to the State's student databases. We decline to expand the timeframe for submitting data corrections from these other systems, as commenters recommended, because the four-working-day timeframe is intended to expedite the period between an SEA's decision to revise data and the revised data being populated in the State's records systems (for subsequent upload to MSIX). Allowing an SEA to submit data to MSIX within 10 working days of the corrected data being entered in the State's records systems would, absent additional regulatory requirements, essentially allow SEAs an unlimited amount of time between making the decision to revise data and entering the revisions in their State data system, thus further delaying the transmission of the necessary data to MSIX. While we recognize the challenges SEAs may face in revising existing processes or procedures, including processes or procedures that are not solely within the control of SEA staff administering the MEP, we firmly believe that the requirements are necessary to ensure that migratory children's records are accurate, up-to-date, and available in a timely manner to school and project staff who need them.

In response to the comment about burdens associated with tracking data-correction requests, we note that the SEA has similar record-keeping responsibilities under other Federal and non-Federal programs (*e.g.,* the record retention requirements contained in 2 CFR 200.333, part of the Uniform Administrative Requirements), and the SEA should already have an efficient record-keeping system that can be extended to this particular requirement. Based on responses to the Department survey of States mentioned previously, we estimated that on average each SEA will receive one data correction request annually. If an SEA receives a substantially larger number of data correction requests, this might indicate a problem with data quality controls.

Section 200.85(e) does not require SEAs to implement specific data-correction request procedures with respect to issues such as how requests must be made and how an SEA will decide whether to revise the data as requested. Thus, each SEA may determine the methods it will employ to receive such requests, how it will investigate requests, and whether and how appeals may be made. The regulations instead require SEAs to respond within specific timeframes (30 calendar days of receipt of the correction request), and require an SEA's written procedures to include minimum action steps (*e.g.,* send a written or electronic acknowledgement to parent/guardian/child requestor and investigate the request). We plan to provide technical assistance and guidance to assist SEAs in developing their written procedures, and our program monitoring will include monitoring of these regulatory requirements.

We agree with the commenters that information about data correction procedures must be communicated in a format and language that is accessible to parents, guardians, and migratory children, including those whose primary language is not English. We will consider providing technical assistance and guidance to SEAs that experience difficulties in communicating with parents. At the same time, we urge those with such concerns to utilize the SEA's existing procedures and resources, as the requirement to communicate with parents in accessible formats and in a language they understand is not a new requirement, but one that has applied to administration of the MEP for years. Section 1304(c)(3)(B) of the ESEA provides that each SEA desiring MEP funds must provide an assurance that ". . . all such programs and projects are carried out . . . in a format and language understandable to the parents." Because these regulations would be part of the overall MEP requirements, we believe that State responses to MSIX data correction requests would be one of the activities in carrying out MEP programs and projects, and therefore would need to be carried out in a format and language understandable to requesters (parents, guardians, and migratory children). As statutory requirements of the MEP, these Federal requirements, like any others, supersede any conflicting State or local laws.

Finally, we do not think it is necessary for the MSIX regulations to reiterate other applicable non-MEP Federal requirements. Those other requirements, including applicable Federal civil rights laws, already apply to the MEP and implementation of MSIX.

Changes: None.

MSIX Data Protection (§ 200.85(f))

Comments: One commenter expressed concerns with the requirements for protection of MSIX data. The commenter expressed concerns about the burden associated with the requirement in § 200.85(f)(2) that SEAs establish and implement written procedures to protect records, and recommended that the Department write the necessary procedures. The commenter also expressed concerns about the requirement in § 200.85(f)(4) that SEAs maintain documentation identifying MSIX users and the authorizing supervisors, suggesting that MSIX be configured to maintain this documentation rather than impose this burden on SEAs.

Two commenters recommended adding to the types of authorized users permitted access by SEAs, which as proposed in the NPRM under § 200.85(f)(2)(i) include authorized users at the SEA, its LOAs, and LEAs in the State that are not LOAs but where a migratory child has enrolled. One commenter recommended that the types of authorized users be broadened, in the interest of including individuals who serve out-of-school youth, but who are not SEA, LOA, or LEA personnel.

One commenter expressed support for the requirements for data protection, and opposed granting access to MSIX data and records to parties, such as other agencies and government bodies, other than the authorized users from entities listed under proposed § 200.85(f)(2)(i). On the other hand, the commenter recommended that the Department consider developing a procedure for parents, guardians, and current or former migratory children to access a child's MSIX record without needing to be granted access to the MSIX system as an authorized user, via the creation of a simple, uniform record request form, available both in paper and online. The commenter further proposed that such a request form be used to produce two possible versions of MSIX records (one more limited than the other), citing the benefits of such a process for college applications, job applications, and applications for Deferred Action for Childhood Arrivals.

Discussion: In response to the commenter's concerns regarding the cost and burden associated with the written procedures required by § 200.85(f)(2), we note that the regulations do not prescribe a single set of procedures for all States. Rather, they allow each SEA the flexibility to design their own State-specific procedures. We have considered ways to alleviate the burden of writing the required procedures, and have developed templates as well as online training and training toolkits for State officials to use. We plan to provide technical assistance to States in utilizing these resources.

In response to the same commenter's recommendation that MSIX maintain the necessary documentation on authorized users required of SEAs under § 200.85(f)(4), we will explore the feasibility of having MSIX generate and maintain this documentation. At this time, the system does not contain this functionality, so we will not now revise § 200.85(f)(4) to eliminate the SEA's responsibility to maintain this documentation. We also note that, although the Department has developed and disseminated an OMB-approved MSIX User Application Form (OMB Control Number 1810–0686), the regulations do not require SEAs to use this form as long as they maintain documentation that contains the information reflected on the OMB-approved form.

We also do not agree that it is appropriate at this time to broaden the types of MSIX authorized users to allow SEAs to permit access beyond those users at the SEA, LOA, or non-MEP funded LEA levels. However, we recognize that there may be benefits to migratory children in allowing certain non-SEA, LOA, or LEA users, including parents, guardians, and current or former migratory children, to access MSIX. The Department will examine the MSIX system of records notice, published in the **Federal Register** under the Privacy Act on December 5, 2007 (72 FR 68572), to consider the costs, benefits, and feasibility of authorizing additional groups of users. Consultation with States, and further study, are needed to assess the potential risks and benefits of broadening the types of authorized users, while ensuring that the system is still being used only for its limited purposes and also affording the maximum benefits to migratory children.

In response to the recommendation for a uniform records request form for parents, guardians, and current and former migratory children to gain access to a child's MSIX record without being granted access to MSIX as an authorized user, we recognize the benefits of enabling parents, guardians, and former and current migratory children to access their MSIX records. However, we believe there are sufficient procedures in place to allow parents, guardians, and migratory children to request a copy of the child's MSIX record. Currently, each LOA and SEA, as well as the Department, has its own procedures for providing migratory children (and parents or guardians of migratory children) a copy of a child's MSIX record. For example, in order to request a copy of the MSIX record from the Department, a requestor must contact the Office of Migrant Education.[4] We encourage migratory children and parents to request such records at the LOA or SEA level prior to submitting such a request to the Department. In addition, we will consider developing more detailed guidance for LOAs and SEAs to make the process for parents, guardians, and migratory students themselves to request the MSIX record as straightforward and user-friendly as possible.

Changes: None.

Comments: One commenter requested the Department to reconsider the current MSIX security measure that blocks MSIX access for authorized users after a 30-day period of inactivity. The commenter was concerned that MSIX authorized users in school districts where migratory children do not enroll regularly will face delays in reactivating access to the system when needed.

Discussion: We appreciate the commenter's recommendation and will look into this matter. However, the comment is outside the scope of our proposed regulations.

Changes: None.

Regulatory Impact: Costs and Burden Associated With the Regulations

Comments: Several commenters expressed concerns about the costs and burden associated with the implementation of the regulations. One commenter acknowledged the benefit of creating a uniform system for the transfer of educational records between school districts, but stated that the costs to SEAs estimated in the NPRM seem too low. The same commenter questioned the lack of data to show how the regulations will directly benefit migratory students academically. One commenter stated that the costs to small States (which we understand to mean States with relatively smaller numbers of migratory children or relatively small annual awards of MEP funds) of implementing these regulations could jeopardize the sustainability of the MEP in those States. One commenter asked the Department to state the amount of funds it plans to allocate to SEAs for planning, implementation, and recurring annual costs of the system; and further requested that, in allocating such funding to SEAs, the Department consider the varying costs of personnel services. One commenter suggested a less costly alternative approach would be to improve the existing records systems currently used by States.

Discussion: We appreciate the commenters' concerns and recommendations, and agree with them in part. In response to the commenter that stated that the estimated costs to SEAs in the NPRM seemed too low, we note that the commenter did not propose a more accurate cost estimate. We have developed the cost estimates based upon consultation with stakeholders, and believe them to be reasonable. We acknowledge that estimates will not be an exact reflection of actual costs borne by each SEA. We are updating the cost and burden estimates to reflect the most current data we have available.

While it is difficult to quantify the benefits of these regulations, including specific academic benefits to migratory children, they will provide important benefits to migratory children and their families and to States and LOAs, as discussed in more detail in the *Regulatory Impact Analysis* section of this document. We issue these regulations on a reasoned determination that they reflect the best way to implement State responsibilities under section 1308(b) of the ESEA, and that the benefits of these regulations will justify their costs. In response to the commenter concerned about the effect of implementation costs on small States, and the commenter that asked the Department to state the amount of funds it plans to allocate to SEAs, we plan to assist States in implementing these regulations through additional technical assistance, guidance, and other resources to alleviate the costs and other burdens imposed on SEAs. In addition, we will consider the feasibility of providing additional funds to SEAs specifically for MSIX implementation purposes, following consultation with MEP grantees. During this consultation process, we will consider information provided by SEAs on the varying additional costs expected as a result of these regulations.

In response to the commenter who recommended the improvement of existing State records systems as a less costly alternative to the requirements contained in these regulations, we are confident that the approach reflected in these regulations will maximize net benefits to migratory children. We encourage all SEAs to improve their existing records systems in order to ensure data quality, and to maximize the benefits to the migratory children whose records are contained in such systems. However, we do not believe that the improvement of individual State systems is an acceptable substitute for the use of MSIX, as provided in these regulations, because MSIX has several unique functions that cannot be realized by individual State systems. Among these unique functions are the consolidation of both intra- and inter-State data into a single Consolidated Student Record; identification of near-matches (*i.e.*, the system identifies possible duplicate records, which are automatically added to "worklists" for the SEA to resolve) from a national pool of migratory children; and timely access to such records anywhere in the Nation.

Changes: We have changed the cost and burden estimates to reflect the most up-to-date data. Updated cost and burden estimates are found in the *Regulatory Impact Analysis* section of the preamble.

Clarity of the Regulations

Comments: One commenter responded to the six bulleted questions regarding clarity of the regulations, found on page 79234 of the NPRM. The commenter stated that the requirements in the proposed regulations were not written in plain language, and those regulations contained technical terms or other wording that interferes with their clarity. The commenter suggested that the Department include a glossary or synopsis understandable to a layperson. The commenter stated that the format of the regulations reduces their clarity, and could be improved by use of shorter sections, spacing, bullets, tables, and charts. For the **SUPPLEMENTARY INFORMATION** section of the preamble, the commenter suggested an outline of the proposed changes, including a synopsis of each change; and bulleted information. Finally, the commenter suggested that the Department could expect to receive more public comments if the information were presented in a clearer format, recommending: A numbered table of proposed changes; a brief description of the proposed changes and the timeframe with a reference to the pages in which the information may be found; full pages rather than columns; spaces between sections; and tables, charts, diagrams, and a table of contents.

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[4] OME may be contacted at: U.S. Department of Education, Office of Migrant Education, 400 Maryland Avenue SW., Washington, DC 20202. Phone: (202) 260–1164. Email: *msix@ed.gov*.

Discussion: We appreciate the commenter's suggestions to improve the clarity of the regulations, and have made every effort to use plain language and present the information clearly in these final regulations. We are required to use a specific format for **Federal Register** documents, so some of the commenter's suggestions, while helpful, are simply not feasible. We will keep the commenter's suggestions in mind for technical assistance and guidance documents that follow publication of the final regulations.

Changes: None.

Paperwork Reduction Act: Costs and Burden Associated With Information Collection

Comments: Four commenters addressed the information collection associated with these regulations in response to the NPRM. Because those four comments were submitted in the NPRM public comment period, we summarize and respond to those four comments here. The Department received four additional comments regarding the information collection, but those comments were submitted in the ICN public comment period for the 72 MDEs, which was filed under a separate docket. In accordance with PRA procedures, those four comments submitted in the ICN public comment period will be addressed separately, in the Department's correspondence with OMB.

One commenter expressed support for the information collection requirements associated with the regulations, stating that the administrative costs and burden are outweighed by the benefits to migratory children.

In response to our statement in the ICR Supporting Statement that there should be no additional record-keeping costs beyond those covered under customary and usual business practices, one commenter contended that these record-keeping costs are a strain for small States with limited funds (particularly for States that have had an increase in numbers of migratory children without a correlating increase in their grant award). Thus, the commenter asserted that, although the regulations might minimize the burden for larger States, they do not do so for small States. One commenter acknowledged that aspects of the proposed collection are necessary and practical, but objected to the timeframes required by the regulations. The commenter stated that the burden estimates and methodology appear to be sound for larger States, but the needs and realities of smaller States with fewer funds are not addressed. The commenter stated that the information collection would, in theory, enhance the quality, usefulness, and clarity of the information collected by the Department, but alternative models would be less burdensome for certain States. (We note that the commenter did not elaborate on the specifics of such alternative models.)

One commenter expressed concern that collecting information for additional MSIX data fields needed for child count or other reporting requirements would impose unnecessary fiscal and labor burdens for States because States would need to fund the process for matching and/or converting data elements from their State student information system to MSIX. The commenter asserted that the collection of such information is not reasonable and necessary because States already have a legitimate, widely acceptable system to provide data to the Department.

Discussion: The Department appreciates the support expressed for the information collection requirements associated with these regulations. We believe that the benefits of the regulations will outweigh the incremental costs that States, including small States, will incur as a result. We note that these requirements stem from our statutory responsibility in section 1308(b) of the ESEA, and are based in large part on our prior consultation with stakeholders, including those from smaller States. We also note that the information collection requirements mandate the data elements that States must collect and maintain, but we do not regulate on the specific methodology that each State must use to collect the necessary data or the systems that States use. Large and small States alike are encouraged to use systems and methods for data collection and record-keeping that they find to be most efficient and cost-effective. We will continue to provide technical assistance and guidance to all States in identifying the most efficient and cost-effective methods for data collection, and facilitate interstate coordination to allow States to share best practices with one another.

In response to the commenter who expressed concerns about the collection of information in MSIX through additional data fields necessary for child count or other reporting purposes, we note that we are not requiring any additional data elements at this time other than MDE 72, the Out-of-State Records Flag, which indicates whether or not one of the State's LOAs have received secondary school records from another State for the secondary school-aged migratory child for whom an SEA has approved a new COE. The information needed for child counts and producing national data on the migratory population is currently collected by States under the ICRs for the Department's EDFacts and CSPR, and based on requirements for the MEP COE and in related regulations. As for other data elements, the process for matching and/or converting data elements from State systems to MSIX, and the associated costs and burden, will be a one-time cost and, other than the new MDE 72, will only apply to the 23 States that have not already undergone such linkage as of June 2015 for all MDEs. Please see the discussion in the *Alternative Methods for Collecting and Reporting Data* section for the Department's rationale for utilizing MSIX to generate a child count and produce national data on the migratory population. We address comments with respect to the timeframes for collecting the required MSIX data in the *MSIX Data Submission Requirements—General Timelines (§ 200.85(b)(1))* section.

Changes: None.

Executive Orders 12866 and 13563

Regulatory Impact Analysis

Under Executive Order 12866, the Secretary must determine whether this regulatory action is "significant" and, therefore, subject to the requirements of the Executive order and subject to review by the Office of Management and Budget (OMB). Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action likely to result in a rule that may—

(1) Have an annual effect on the economy of $100 million or more, or adversely affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities in a material way (also referred to as an "economically significant" rule);

(2) Create serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles stated in the Executive order.

This final regulatory action is a significant regulatory action subject to review by OMB under section 3(f) of Executive Order 12866.

We have also reviewed these regulations under Executive Order 13563, which supplements and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, Executive Order 13563 requires that an agency—

(1) Propose or adopt regulations only on a reasoned determination that their benefits justify their costs (recognizing that some benefits and costs are difficult to quantify);

(2) Tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives and taking into account—among other things and to the extent practicable—the costs of cumulative regulations;

(3) In choosing among alternative regulatory approaches, select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity);

(4) To the extent feasible, specify performance objectives, rather than the behavior or manner of compliance a regulated entity must adopt; and

(5) Identify and assess available alternatives to direct regulation, including economic incentives—such as user fees or marketable permits—to encourage the desired behavior, or provide information that enables the public to make choices.

Executive Order 13563 also requires an agency "to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible." The Office of Information and Regulatory Affairs of OMB has emphasized that these techniques may include "identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes."

We are issuing these final regulations only on a reasoned determination that their benefits justify their costs. In choosing among alternative regulatory approaches, we selected those approaches that maximize net benefits. Based on the analysis that follows, the Department believes that these regulations are consistent with the principles in Executive Order 13563.

We also have determined that this regulatory action does not unduly interfere with State, local, or tribal governments in the exercise of their governmental functions.

In accordance with both Executive orders, the Department has assessed the potential costs and benefits, both quantitative and qualitative, of this regulatory action. The potential costs associated with this regulatory action are those resulting from statutory requirements and those we have determined as necessary for administering the Department's programs and activities.

In this regulatory impact analysis we discuss the need for regulatory action, and the potential costs and benefits. The need for this regulatory action is based on statutory requirements that SEAs provide for educational continuity through the timely transfer of pertinent school records when migratory children move from one school to another, regardless of whether such move occurs during the regular school year (see section 1304(b)(3) of the ESEA), as well as the statutory requirements that the Secretary: (a) Assist States in the electronic transfer of student records, and (b) ensure the linkage of migrant student records systems for the purpose of electronically exchanging, among the States, health and educational information regarding all migratory students (see section 1308(b) of the ESEA). We have used the most up-to-date data available to estimate the burden of these regulations on SEAs and have considered ways to alleviate this burden. We have concluded that the costs of these regulations are outweighed by the benefits to migratory children of having up-to-date educational and health information for all migratory children available on a timely basis in order to facilitate school enrollment, grade and course placement, credit accrual, and participation in the MEP.

Need for Regulatory Action

The Secretary believes that the regulations are necessary for the Department to effectively implement the requirement in section 1308(b) of the ESEA that the Secretary ensure the linkage of migrant student record systems and for the effective implementation of the MEP by States and LOAs serving migratory children. This congressionally mandated records transfer system will help SEAs, LEAs, and LOAs meet the needs of migratory children by having complete, accurate, and up-to-date educational and health information immediately available to school and program staff where migratory children enroll after they move.

Until now, all but one State receiving MEP funds has voluntarily entered some MDEs into MSIX. However, there is not consistency in the timeframes within which States enter these data, or in the completeness of data that each State enters for its migratory children. These regulations establish basic rules governing the collection of MDEs that States receiving MEP funds will need to submit to MSIX, so that when migratory children move and enroll in new schools and programs, staff in those schools and programs may make timely and appropriate decisions to facilitate school enrollment, grade and course placement, accrual of secondary course credits, and participation in the MEP.

Under the regulations, States receiving MEP funds will need to provide three categories of MDEs: (1) Core data elements (which include demographic and enrollment data), (2) assessment data, and (3) course history data (which under the regulations pertain only to secondary school-aged children).

Potential Costs and Benefits

We have updated the cost and burden estimates contained in this section to reflect the availability of more up-to-date data from MSIX, CSPRs, and the U.S. Bureau of Labor Statistics National Compensation Survey: Occupational Earnings in the United States. As described in the following paragraphs, the Department estimates that the total cost to participating SEAs of implementing these regulations is approximately $17,363,639 for the first year, and $16,431,718 annually thereafter. The estimated burden per migratory child, amortized over three years, is approximately one hour and 30 minutes, at an approximate cost of $46.50 per year. These estimates cover all regulatory requirements, including the costs of information collection activities, which are discussed separately under the heading *Paperwork Reduction Act of 1995*. Estimates are based on the initial three-year period for which we anticipate OMB will approve the information collection associated with these regulations.

As of July 2015, of the 47 States that currently receive MEP funds: 27 States have provided complete start-up submissions for all MDEs; 19 States have provided partial start-up submissions; and one State has not provided any data to MSIX. Three of the 50 States (not including the District of Columbia, the Commonwealth of Puerto Rico, or the outlying areas) do not currently receive MEP funds or identify migratory children, and MDEs for migratory children in those States are not being updated in MSIX. Although 47 States currently receive MEP funds, our burden estimates are based on 50 States, in order to account for possible burden increases should all three of the currently non-participating States choose to participate in the MEP during the first three years that the regulations become effective. We do not anticipate that the District of Columbia, the Commonwealth of Puerto Rico, or the outlying areas will participate in the MEP in the first three years that the regulations become effective, given that none of these entities have participated in the MEP in the previous decade. Basing the estimate on 50 States is consistent with the NPRM. The first-year estimate excludes start-up costs that have already been incurred by participating SEAs since MSIX began operating in 2007, as well as costs for using records, data quality, data protection, and data correction (activities required under § 200.85(c)-(f)) for those 27 States that have provided complete start-up submissions.

These costs will not all be borne by the States and their LOAs; the Department provides both monetary and non-monetary resources to assist States in implementing MSIX activities successfully. For example, in 2007, the Department paid contractors to work with States to develop system interfaces that connect State data systems housing migrant student data to MSIX. In 2008 and 2010, the Department provided funding to States under the MSIX Data Quality grant program that could be used for developing these interfaces, improving the quality of migrant student data, and developing and implementing procedures for submitting data to MSIX. Pending consultation with States, the Department may provide similar resources in the future to assist in the implementation of these regulations. In addition, the Department has provided extensive technical assistance to States on issues of data quality and security, most recently to 23 States through the MSIX Data Quality Initiative (DQI), but also through the State Longitudinal Data System program and as part of the implementation of the *EDFacts* system. Each of these activities reduced the costs of implementing these regulations. Further, and most importantly, States may use MEP funds to cover the costs associated with implementing the regulations (albeit with the result that funding is then unavailable for other MEP activities). A more detailed discussion of the costs of each regulatory requirement follows.

To help calculate the time estimates associated with the data submission requirements, the Department used the median number of minutes provided in March 2012 by officials in eight of the nine States with varying numbers of migratory children surveyed regarding the time it takes them to collect and enter these data in their State data systems. Estimates of the numbers of migratory children for whom States will submit information to MSIX were derived from CSPRs for the 2013–2014 performance period and include the number of migratory children ages 0–21 that States reported as MEP-eligible in performance period 2013–2014 (364,227); the number of MEP-eligible K–12 children enrolled in school (269,538); the number of MEP-eligible secondary school students (76,008); and the number of MEP-eligible students reported as having taken State assessments (78,865). The hourly cost used for these estimates was $35.67, the mean hourly earnings for State and local government management, professional, and related occupations reported in June 2015 by the U.S. Bureau of Labor Statistics in its National Compensation Survey: Occupational Earnings in the United States.

We estimate that the one-time cost for providing start-up submissions to MSIX under § 200.85(b)(2), excluding costs that were incurred by States before these regulations, is approximately $324,685.

That figure assumes that State and local officials take approximately 53 minutes per migratory child to collect, enter into the State data system, and submit to MSIX general demographic and enrollment MDEs that pertain to all migratory children who have been documented by the State as MEP-eligible; approximately 5 minutes per student for the MDEs pertaining only to migratory students who participate in State assessments; and approximately 55 minutes per student for the course history MDEs pertaining only to migratory secondary school students. Although we expect that the aforementioned revision made in these final requirements for start-up data submissions will reduce burden for States compared to the proposed requirements, the burden estimates are, consistent with the NPRM, based on the numbers of eligible migratory children reported by States in the CSPR. States report the number of eligible migratory children who resided in their State for at least one day during the entire performance period, rather than the number of eligible migratory children that resided in their State on a specific date. Therefore, the burden estimates for start-up submissions are likely to be over-estimates, but we believe this is preferable to under-estimating the burden.

We estimate that the annual costs for complying with § 200.85(b)(3), which covers subsequent submissions to MSIX of data on migratory children for whom an SEA has approved a new COE, updates to MSIX at the end of every school term, and updates to MSIX if a receiving State or LOA notifies a sending State or LOA that a migratory child has moved, will be approximately $16,196,509.

Within that estimate, we estimate the annual costs of implementing the requirements under § 200.85(b)(3)(i), covering collection and submission of data to MSIX for migratory children for whom an SEA has approved a new COE, at $6,717,174. We estimate the annual number of migratory children for whom an SEA has approved a new COE to be 115,415, based on the number of qualifying moves for migratory children that States reported to the Department in section 2.3.1.5 of the CSPR for school year 2013–2014. The number of migratory children for whom an SEA has approved a new COE and for whom there will be MDEs pertaining to assessment data (24,990) and secondary schooling (22,753) is based on the proportion of those students in the population of migratory children enrolled in grades K–12 during school year 2013–2014. We assume the same time estimates used for calculating burden for collecting and submitting data for start-up submissions as are assumed for the calculations of other proposed data submission requirements under § 200.85(b)(2). Based on responses to the Department's survey of States discussed above, we also estimate an additional effort of 1 hour and 10 minutes per student to collect data elements for a secondary student who previously attended another secondary school in the same State (§ 200.85(b)(3)(i)(B)(*1*)) and another 42 minutes to determine if, and notify MSIX when, a LOA has received secondary school records from out of State for a secondary school-aged migratory child for whom an SEA has approved a new COE (§ 200.85(b)(3)(i)(B)(*2*)).

The cost estimate for implementing the requirements under § 200.85(b)(3)(ii), end of term submissions, is $9,312,332. The estimate assumes that States update

MDEs for every migratory child once over the course of each year for most, but not all, of the MDEs pertaining to all migratory children, and that the effort will take approximately 42 minutes per migratory child. This estimated burden, based on the experience of Department staff who have worked on migrant programs at the State level, also assumes a smaller burden for this effort than that for start-up data submissions because some States have developed automated processes for collecting this information and providing these updates to MSIX.

Many of the MDEs in a migratory student's record must be updated every year; for example, when a student finishes a grade level, the student must be marked as "withdrawn" from that grade, and when the student enters the following grade the next school year the student is then marked as "enrolled" in the new grade. Indeed, States may update a student's MSIX record throughout the school year, but will likely need to do so only once a year. There are a smaller number of MDEs, such as birth city, that would not require an update. The end of term cost estimate assumes that States will need five minutes per affected student for the MDEs pertaining to State assessments, as those assessments are administered once a year. The Department's estimate also assumes 55 minutes per migratory student for the MDEs pertaining only to migratory secondary school students, in accordance with the surveyed States' estimated average burden for MDEs for secondary school students regardless of the number of courses in which secondary school students were enrolled.

The estimate for the annual costs of implementing the requirements under § 200.85(b)(3)(iii), change of residence submissions, is approximately $167,002. This estimate is based on the 2,497 requests that receiving States or LOAs (*i.e.,* States or LOAs where migratory children moved) made through MSIX in the 2013–2014 school year to request records from sending States or LOAs (*i.e.,* a child's previous place of enrollment). Apart from the end of term data submission requirements, the regulations require a sending State to update a student record only if it receives notification from a receiving State or LOA through MSIX that it has enrolled a migratory child formerly enrolled in the sending State. However, the regulations do not require receiving States (or their LOAs) to notify the migratory child's former location that the migratory child has changed residence. This allows a State or LOA enrolling a migratory child flexibility to send a notification (through MSIX) to a child's former location, requesting an updated student record, only if the child's MSIX record is missing data.

Furthermore, § 200.85(b)(3)(ii) requires SEAs to update MSIX MDEs at the end of each term; therefore, States and LOAs are more likely to use MSIX to request records from a previous location under § 200.85(b)(3)(iii) for children moving in the middle of the term. An analysis of MSIX data on the timing of migratory child moves during school year 2013–2014 showed that approximately 59 percent of the moves occurred during the summer months, after the end of the school year. Including January moves, 65 percent of all moves occur between terms, which should limit the number of data submissions required under the change of residence provision in § 200.85(b)(3)(iii).

The estimate for the total costs of implementing the requirements under § 200.85(c), using Consolidated Student Records contained in MSIX; § 200.85(d), establishing rules pertaining to the quality of data submitted to MSIX; and § 200.85(f), establishing rules pertaining to the protection of data submitted to MSIX, is approximately $841,309 for the first year and $234,072 for each subsequent year. The main costs for implementing these requirements are associated with the time that will be needed for States to establish policies and procedures to address the use of MSIX, data quality, and data protection; develop and disseminate the guidance and procedures to State and local personnel; and provide training to State and local personnel who have access to MSIX. Many of these costs will be one-time costs.

To minimize the burden on States of implementing these requirements, the Department developed a template for a State manual that we believe will assist States in developing policies and procedures for using MSIX, ensuring data quality, and protecting the data. The Department also developed online training and a training toolkit that State officials may choose to use in carrying out training within their States. Based on the experience of Department staff who have worked on migrant programs at the State level, we estimate that each State will spend approximately 120 hours developing policies and procedures with the aid of the template. Using the same cost per hour used for the data submission requirements, the total one-time cost of establishing policies and procedures will be an estimated $59,926. To calculate the costs of training State and local personnel in the use of MSIX and associated policies and procedures, we estimate 3.5 person-hours per State for using the Department's training toolkit to develop and conduct training for MSIX users—up to 4 training of trainer sessions plus each MSIX user spending 2 hours completing training. We estimate 3,525 individuals will complete training during year 1 and approximately 370 additional individuals will complete training each subsequent year. This estimate is based on 2,820 current active users, which is expected to increase by 25 percent during the first year these regulations are implemented and by 10 percent for each of the following two years. Based on the same cost per hour used for the data submission requirements, the total training cost is an estimated $276,443 for the first year and $51,374 each subsequent year.

In addition, State personnel will likely need the assistance of an information technology professional to run reports and monitor the data collected and submitted to MSIX, review system security, and work with other State or local personnel to remedy any data concerns or problems. We estimate that, for States that have not fully implemented MSIX, it will take 32 hours per month per State for one information security analyst, and that for other States it will take 8 hours per month. At $36.59 an hour (the mean hourly earnings for information security analysts in State government, excluding schools and hospitals, reported by the U.S. Bureau of Labor Statistics in its National Compensation Survey: Occupational Earnings in the United States, 2014), we estimate the services of these information security analysts will cost $323,163 for year 1 and, assuming all States are fully implementing MSIX by the end of year 1, $175,632 each subsequent year. The estimate includes an additional $128,968 for complying with § 200.85(c), which concerns use of MSIX's consolidated student records, to meet costs associated with development of electronic interfaces and communications between State data systems and MSIX. The Department provided resources to assist States with this work, as discussed earlier, and estimates that the burden associated with doing this work is approximately 1,816 hours for States that have not fully implemented MSIX and 1,800 hours for all States to implement the new MDE. The estimate further includes $52,809 for complying with the requirement in § 200.85(f) that MSIX users fill out user application forms. We estimate completing the form will take 5 minutes, and a supervisor will take 20 minutes to review a user application form and other documentation to determine whether to grant access to MSIX to an applicant. In total, we estimate it will take 25 minutes to grant access to each user. The cost estimate is based on 3,525 users for year 1 (as discussed previously) and the same labor cost as that used to calculate the proposed data submission requirements. For subsequent years the cost is approximately $5,545 based on an estimated additional 370 users per year.

The estimated cost of implementing the requirements under § 200.85(e), procedures for MSIX data correction by parents, guardians, and migratory children, is approximately $1,137. Based on responses to the Department's survey of States discussed above, we estimate each State will receive one request to correct data per year and that each request will take approximately 38 minutes to acknowledge, review, make any necessary corrections to the data, and notify the requester of the resolution to the request. In addition, based on prior experience, we estimate the Department will receive six data correction requests per year from parents, guardians, or migratory children, and anticipate that States will similarly require an average of 38 minutes to address any Department requests on this matter. The cost per hour used is the same as that used to estimate start-up data submissions.

While it is difficult to quantify the benefits of these regulations, we believe that they will provide important benefits to migratory children and their families, States, and LOAs, particularly for the approximately 32 percent of migratory children who make an MEP-qualifying move across school district boundaries each year (based on State CSPR data for performance period 2013–2014). Instantaneous access to records of children who have previously been identified as MEP-eligible will reduce the time it takes school personnel to enroll those children in new schools and place them in appropriate classes. Prompt placement is necessary not only to ensure continuity of education, but also to ensure that migratory children receive the maximum benefits from the school's regular program as well as MEP services, as the MEP limits the amount of time that migratory children may receive services. In addition, prompt access to records reduces the likelihood of duplication of services and helps ensure that migratory children are placed in the right classes, which reduces the likelihood that a child will repeat classes or be placed in an inappropriate class, and thus also the likelihood that the child will suffer academically and emotionally. For secondary school students, having a record documenting credit accrual increases the likelihood that a migratory child will graduate from high school on time. In addition, instant access to records of children who have previously been identified as MEP-eligible will assist school districts and states in complying with their federal civil rights obligations to ensure that all students, regardless of background, have timely and equal access to educational opportunities. And because migrant students often enroll without adequate, and in many cases any, documentation of their educational and health history, full MSIX implementation will help school districts and states ensure that students are not chilled or discouraged from accessing educational opportunities because of lack of documentation or because of their actual or perceived immigration status.

As MSIX includes information about where immunization records are available, it helps prevent duplication of vaccinations, an unnecessary additional expense for families and community health systems. Most States require students to be vaccinated, at a minimum, for polio, diphtheria, tetanus, pertussis, measles, mumps, rubella, hepatitis B, and varicella. The combined cost per dose as of July 2015 for these pediatric vaccinations under the Center for Disease Control vaccine contracts (established for the purchase of vaccines by immunization programs that receive CDC immunization grant funds, such as State health departments) was approximately $153, and the average cost of the same vaccines to the private sector was approximately $230. Reducing duplicate vaccinations also preserves the vaccine supply for others in the community. In addition, MSIX incorporates a flag for students with acute or chronic medical conditions, thus instantly alerting authorized MSIX users to the fact that a migratory child may need additional support services and referrals to medical care.

We further note that these regulations were informed by the Department's and the States' previous experience implementing a migrant student record transfer service from the 1970s through the 1990s. The Migrant Student Record Transfer System (MSRTS) was a national, computer-based system for records collection and transfer established in response to a 1969 congressional mandate requiring the creation of a service for transmitting educational and health records for migrant students. MSRTS was terminated in 1995 due to concerns about the accuracy and usefulness of the data in the system, and the lack of uniformity in the data that States reported to the system. In addition, many users considered MSRTS too slow and burdensome, as the computer technology relied largely on a paper-based system for collecting and reporting information that did not incorporate technological advancements efficiently. These regulations are designed to ensure that MSIX users have ready access to complete, trustworthy, up-to-date records.

The requirement that agencies serving migratory children use MSIX and the Consolidated Student Records MSIX generates will ensure not only that information in MSIX is used, but also that State and LOAs acquire an interest in ensuring the quality and timeliness of the data they provide to and obtain from the system. Other benefits include access to Consolidated Student Records that are current, accurate, complete, and secure, and that contain data that may be currently maintained in different systems within States; for example, State assessment data may not be maintained in the same system as student health records. States' previously voluntary participation in MSIX reflects the value they see in having this information on migratory children in one centralized location, which enables them to better serve one of their most vulnerable populations.

For these reasons, the Department believes that the benefits of these regulations will significantly exceed the estimated costs, much of which would be met with Federal resources.

Elsewhere in this section under *Paperwork Reduction Act of 1995,* we identify and explain burdens specifically associated with information collection requirements.

Paperwork Reduction Act of 1995

Section 200.85 contains information collection requirements. Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3507(d)), the Department has submitted a copy of this section as part of the Information Collection Request (ICR) package to OMB for its review. An approved OMB control number will be assigned to this new ICR following the publication of the final rule.

A Federal agency may not conduct or sponsor a collection of information unless OMB approves the collection under the PRA and the corresponding information collection instrument displays a currently valid OMB control number. Notwithstanding any other provision of law, no person is required to comply with, or is subject to penalty for failure to comply with, a collection of information if the collection instrument does not display a currently valid OMB control number.

MDEs consist of 72 data elements that reflect the minimal educational and health information needed to ensure proper enrollment, grade and course placement, accrual of secondary course credits, and participation in the MEP for migratory children. The MDEs, and the various information sources through which they are currently obtained, would not change as a result of these regulations except for the collection of one new MDE, the Out-of-State Records Flag, which only applies to secondary school-aged migratory children for whom an SEA has approved a new COE. The Out-of-State Records Flag indicates whether one of the State's LOAs has received records from a secondary school attended previously in another State, by the secondary school-aged migratory child for whom an SEA has approved a new COE. The MDE does not require SEAs or LOAs to collect and submit the out-of-state secondary school records to MSIX, but simply to indicate whether or not an LOA has obtained such records.

Thirty of the MDEs are collected and entered into State data systems through the ICRs for the Department's EDFacts (OMB Control Number 1875–0240, approval first granted October 17, 2007) and for the MEP COE and related regulations (OMB Control Number 1810–0662, COE approval first granted September 5, 2008). We do not account here for the burden of collecting, maintaining, and submitting to MSIX these 30 MDEs because these MDEs are already collected and maintained for other purposes, and we have assumed that submission of these MDEs to MSIX will occur automatically once a State's electronic interface with MSIX has been established.

Forty-one of the remaining 42 MDEs are collected and entered into the State data systems under the existing MSIX ICR (OMB Control Number 1810–0683). These regulations create a new MDE. The regulations also specify the parties to whom the collection applies as well as establish specific timelines for data collection and submission to MSIX. As a result, we have amended and restated the MSIX ICR to reflect, among other things, a new burden analysis and supporting statement.

Section 200.85—Responsibilities of SEAs for the Electronic Exchange Through MSIX of Specified Educational and Health Information of Migratory Children.

Section 200.85 requires SEAs to collect, maintain, and submit to MSIX educational and health information on migratory children. This information will enable SEAs and their LOAs to reduce educational disruptions for migratory children, make timely and accurate school placements, ensure academic credit for school work completed, streamline academic progression toward graduation requirements, and promote the use of complete academic records as needed for postsecondary education and employment opportunities. The exchange of health-related information through MSIX will also help reduce unnecessary immunizations of migratory children which might otherwise occur due to lack of timely, accurate health information.

Estimates of Annualized Burden to SEA Respondents

For the 42 MDEs not covered by other ICRs, the total burden for all SEA respondents in the first three years after the effective date of the regulations is estimated at 463,803 hours per year. This amounts to an average of 9,276 hours per year for each of the 50 SEAs. Because the number of MEP-eligible children varies greatly among the States, we have estimated the overall burden as 1,273 hours annually per 1,000 MEP-eligible children to enable individual SEAs to assess the burden of the information collection.

These estimates were developed by program and contract staff with experience in the State-level administration of the MEP, based upon consultation with States, analysis of the information reported by each State in its 2013–2014 CSPR (OMB Number 1810–0614), and State data submitted previously to MSIX. The estimated burden to collect the MDEs includes the effort to enter the data in the appropriate State information systems for electronic transmission to MSIX.

In calculating the burden of this information collection, we have not included the burden associated with start-up submissions previously made to MSIX in whole or in part. In calculating the burden associated with subsequent data submissions, our estimates quantify the total annualized burden to SEAs, and do not specify the incremental burden to those SEAs that have previously collected, maintained, and submitted to MSIX any or all of the MDEs covered by the MSIX ICR relating to subsequent data submissions.

See the discussion below for a further explanation of the burden related to specific regulatory provisions.

Start-up Data Submissions (§ 200.85(b)(2))

As of June 2015, 27 States had already met the requirement to collect and submit to MSIX MDEs for every MEP-eligible child in the State; an additional 19 States had provided partial start-up submissions; and 4 States have not provided any start-up submission data to MSIX. We used these figures for our calculations of start-up data submissions. Submissions of MDEs needed as start-up data is a one-time requirement for each SEA; submissions are required to be completed no later than 90 calendar days after the effective date of the final regulations. Amortized over three years, the annualized burden of the requirement for the remaining 23 States is estimated to be 9,102 hours per year in total and 396 hours per year per SEA. All subsequent data submission requirements are covered by the other information collection activities described below.

Migratory Children for Whom an SEA Has Approved a New COE (§ 200.85(b)(3)(i)(A))

The annualized burden to implement the requirement for 50 States to collect and submit the MSIX MDEs within 10 days of newly documenting the eligibility of each migratory child is estimated at 123,928 hours per year in total and 2,479 hours per SEA. Documenting the eligibility of migratory children is an ongoing process, and we estimate the burden would remain at a constant level in each of the three years that this information collection covers.

Migratory Children for Whom an SEA Has Approved a New COE With Prior Secondary School Records in the Same State (§ 200.85(b)(3)(i)(B)(1))

The annualized burden of the requirement for SEAs to collect and submit to MSIX MDEs from the most recent secondary school attended previously within the State is estimated at 26,545 hours per year in total and, on average, 531 hours per year per SEA. Collecting and submitting in-State secondary school information for migratory children for whom an SEA has approved a new COE is an ongoing process, and we estimate the burden would remain at a constant level in each of the three years that this information collection covers.

Migratory Children for Whom an SEA Has Approved a New COE With Secondary School Records From Another State (§ 200.85(b)(3)(i)(B)(2))

The annualized burden of the requirement for SEAs to notify MSIX within 30 days of obtaining out-of-state secondary school records for a migratory child for whom an SEA has approved a new COE is estimated at 38,441 hours per year in total, and to average 769 hours per year for each SEA. Our burden estimate includes a one-time effort for each State to modify its State data system and MSIX interface to collect and submit a new MDE to indicate whether an LOA has out-of-state school records for a secondary school-aged migratory child for whom an SEA has approved a new COE (this one-year effort is amortized over the three years of the collection). Documenting migratory children is an ongoing process, and we therefore estimate that the burden will remain constant for each of the three years this information collection covers.

End of Term Submissions (§ 200.85(b)(3)(ii))

The annualized burden of the requirement to collect and submit updated and newly available MDEs to MSIX within 30 days after the end of each educational term for all migratory children is estimated at 261,069 hours per year in total, and to average 5,221 hours per year per SEA. This is an ongoing process, and we therefore estimate that the burden will remain constant for each of the three years this information collection covers.

Notice of Change of Residence Submissions (§ 200.85(b)(3)(iii))

The annualized burden of the requirement to collect and submit to MSIX all new and updated MDEs within four working days of receiving notification from MSIX that a migratory child has changed residence is estimated at 4,682 hours per year in total, and to average 94 hours per year per SEA. This is an ongoing process, and we therefore estimate the burden will remain constant for each of the three years this information collection covers.

Parental Request to SEAs for MSIX Data Correction (§ 200.85(e)(1)(ii))

The annualized burden for SEAs to submit revised data to MSIX within 4 working days of the decision to correct previously submitted data following a request from a parent, guardian, or migratory child is estimated at 32 hours per year in total, and on average .6 hours per year per SEA. This is an ongoing process, and we therefore estimate the burden will remain constant for each of the three years this information collection covers.

Parental Request to the Department for MSIX Data Correction (§ 200.85(e)(3))

The annualized burden for SEAs to respond within 10 working days to a request for information from the Department in order for the Department to respond to an individual's request to correct or amend a Consolidated Student Record under the Federal Privacy Act is estimated at four hours per year in total, and on average 0.1 hour per year per SEA. This is an ongoing process, and we therefore estimate the burden will remain constant for each of the three years the information collection covers.

Collection of Information

Reporting activity	Description	Total burden
1. Start-up Data Submission § 200.85(b)(2)	Collect and submit to MSIX all MDEs applicable to child's age and grade level for every migratory child eligible to receive MEP services in the State on the effective date of these regulations, other than through continuation of services provided under section 1304(e) of the ESEA.	9,102
2. Migratory Children for Whom an SEA has Approved a New COE § 200.85(b)(3)(i)(A).	Collect and submit to MSIX all MDEs applicable to child's age and grade level for migratory children for whom an SEA has approved a new COE.	123,928
3. Migratory Children for Whom an SEA has Approved a New COE with Secondary School Records in the Same State § 200.85(b)(3)(i)(B)(*1*).	Collect and submit all applicable MDEs from the most recent secondary school previously attended within the same State by the secondary school-aged migratory child for whom an SEA has approved a new COE.	26,545
4. Migratory Children for Whom an SEA has Approved a New COE with Secondary School Records from Another State § 200.85(b)(3)(i)(B)(*2*).	Notify MSIX if one of its local operating agencies obtains records from a secondary school previously attended in another State by the secondary school-aged migratory child for whom an SEA has approved a new COE.	38,441
5. End of Term Submissions § 200.85(b)(3)(ii)	Collect and submit to MSIX all MDE updates and newly available MDEs for migratory children who were MEP-eligible during the term and for whom the SEA previously submitted data.	261,069
6. Change of Residence Submissions § 200.85(b)(3)(iii)	Collect and submit to MSIX all newly available MDEs and MDE updates that have become available to the SEA or one of its local operating agencies.	4,682
7. Parental Request for MSIX Data Correction § 200.85(e)(1)(ii).	If an SEA determines that data previously submitted to MSIX should be corrected as the result of a request from a parent, guardian, or migratory child, the SEA must submit revised data.	32
8. Response to the Department § 200.85(e)(3)	Submit information requested by the Department needed to respond to an individual's request to amend a Consolidated Student Record under the Privacy Act.	4

Intergovernmental Review

This program is subject to the requirements of Executive Order 12372 and the regulations in 34 CFR part 79. One of the objectives of the Executive order is to foster an intergovernmental partnership and a strengthened federalism. The Executive order relies on processes developed by State and local governments for coordination and review of proposed Federal financial assistance. This document provides early notification of our specific plans and actions for this program.

Assessment of Educational Impact

In the NPRM we requested comments on whether the proposed regulations would require transmission of information that any other agency or authority of the United States gathers or makes available. Based on the response to the NPRM and on our review, we have determined that these final regulations do not require transmission of information that any other agency or authority of the United States gathers or makes available.

Federalism

Executive Order 13132 requires us to ensure meaningful and timely input by State and local elected officials in the development of regulatory policies that have federalism implications. "Federalism implications" means substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

In the NPRM we identified a specific section (§ 200.85) that may have federalism implications and encouraged State and local elected officials to review and provide comments on the proposed regulations. In the *Analysis of Comments and Changes* section of this preamble, we discuss any comments we received on this subject.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (*e.g.*, braille, large print, audiotape, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**.

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You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov*. Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department. (Catalog of Federal Domestic Assistance Number: 84.011 Title I, Education of Migratory Children)

List of Subjects in 34 CFR Part 200

Education of disadvantaged, Elementary and secondary education, Grant programs-education, Indians-education, Infants and children, Juvenile delinquency, Migrant labor, Private schools, Reporting and recordkeeping requirements.

Dated: May 3, 2016.

John B. King, Jr.,

Secretary of Education.

For the reasons discussed in the preamble, the Secretary of Education amends part 200 of title 34 of the Code of Federal Regulations as follows:

PART 200—TITLE I—IMPROVING THE ACADEMIC ACHIEVEMENT OF THE DISADVANTAGED

■ 1. The authority citation for part 200 continues to read as follows:

Authority: 20 U.S.C 6301 through 6578, unless otherwise noted.

■ 2. Section 200.81 is amended by:

■ a. Redesignating paragraphs (h) through (k) as paragraphs (m) through (p).

■ b. Redesignating paragraph (g) as paragraph (j).

■ c. Redesignating paragraphs (d) through (f) as paragraphs (f) through (h).

■ d. Redesignating paragraphs (b) and (c) as paragraphs (c) and (d), respectively.

■ e. Adding new paragraphs (b), (e), (i), (k), and (l).

The additions read as follows:

§ 200.81 Program definitions.

* * * * *

(b) *Consolidated Student Record* means the MDEs for a migratory child that have been submitted by one or more SEAs and consolidated into a single, uniquely identified record available through MSIX.

* * * * *

(e) *Migrant Student Information Exchange (MSIX)* means the nationwide system administered by the Department for linking and exchanging specified educational and health information for all migratory children.

* * * * *

(i) *Minimum Data Elements (MDEs)* means the educational and health information for migratory children that the Secretary requires each SEA that receives a grant of MEP funds to collect, maintain, and submit to MSIX, and use under this part. MDEs may include—

(1) Immunization records and other health information;

(2) Academic history (including partial credit), credit accrual, and results from State assessments required under the ESEA;

(3) Other academic information essential to ensuring that migratory children achieve to high academic standards; and

(4) Information regarding eligibility for services under the Individuals with Disabilities Education Act.

* * * * *

(k) *MSIX Interconnection Agreement* means the agreement between the Department and an SEA that governs the interconnection of the State migrant student records system(s) and MSIX, including the terms under which the agency will abide by the agreement based upon its review of all relevant technical, security, and administrative issues.

(l) *MSIX Interconnection Security Agreement* means the agreement between the Department and an SEA that specifies the technical and security requirements for establishing, maintaining, and operating the interconnection between the State migrant student records system and MSIX. The MSIX Interconnection Security Agreement supports the MSIX Interconnection Agreement and documents the requirements for connecting the two information technology systems, describes the security controls to be used to protect the systems and data, and contains a topological drawing of the interconnection.

* * * * *

■ 3. Section 200.84 is revised to read as follows:

§ 200.84 Responsibilities for evaluating the effectiveness of the MEP and using evaluations to improve services to migratory children.

(a) Each SEA must determine the effectiveness of its MEP through a written evaluation that measures the implementation and results achieved by the program against the State's performance targets in § 200.83(a)(1), particularly for those students who have priority for service as defined in section 1304(d) of the ESEA.

(b) SEAs and local operating agencies receiving MEP funds must use the results of the evaluation carried out by an SEA under paragraph (a) of this section to improve the services provided to migratory children.

(Authority: 20 U.S.C. 6394)

■ 4. Section 200.85 is revised to read as follows:

§ 200.85 Responsibilities of SEAs for the electronic exchange through MSIX of specified educational and health information of migratory children.

(a) *MSIX State record system and data exchange requirements.* In order to receive a grant of MEP funds, an SEA must collect, maintain, and submit to MSIX MDEs and otherwise exchange and use information on migratory children in accordance with the requirements of this section. Failure of an SEA to do so constitutes a failure under section 454 of the General Education Provisions Act, 20 U.S.C. 1234c, to comply substantially with a requirement of law applicable to the funds made available under the MEP.

(b) *MSIX data submission requirements*—(1) *General.* (i) In order to satisfy the requirements of paragraphs (b)(2) and (3) of this section, an SEA that receives a grant of MEP funds must submit electronically to MSIX the MDEs applicable to the child's age and grade level. An SEA must collect and submit the MDEs applicable to the child's age and grade level, regardless of the type of school in which the child is enrolled (*e.g.*, public, private, or home school), or whether a child is enrolled in any school.

(ii) For migratory children who are or were enrolled in private schools, the SEA meets its responsibility under paragraph (b)(1)(i) of this section for collecting MDEs applicable to the child's age and grade level by advising the parent of the migratory child, or the migratory child if the child is emancipated, of the necessity of requesting the child's records from the private school, and by facilitating the parent or emancipated child's request to the private school that it provide all necessary information from the child's school records—

(A) Directly to the parent or emancipated child, in which case the SEA must follow up directly with the parent or child; or

(B) To the SEA, or a specific local operating agency, for forwarding to MSIX, in which case the SEA must follow up with the parent, emancipated child, or the private school to make sure that the records requested by the parent or emancipated child have been forwarded.

(iii) For migratory children who are or were enrolled in home schools, the SEA meets its responsibility under paragraph (b)(1)(i) of this section for collecting MDEs applicable to the child's age and grade level by requesting these records, either directly or through a local operating agency, directly from the parent or emancipated child.

(2) *Start-up data submissions.* No later than 90 calendar days after the effective date of these regulations, an SEA must collect and submit to MSIX each of the MDEs described in paragraph (b)(1)(i) of this section applicable to the child's age and grade level for every migratory child who is eligible to receive MEP services in the State on the effective date of these regulations, other than through continuation of services provided under section 1304(e) of the ESEA.

(3) *Subsequent data submissions.* An SEA must comply with the following timelines for subsequent data submissions throughout the entire calendar year whether or not local operating agencies or LEAs in the State are closed for summer or intersession periods.

(i) *Migratory children for whom an SEA has approved a new Certificate of Eligibility.* For every migratory child for whom an SEA approves a new Certificate of Eligibility under § 200.89(c) after the effective date of these regulations—

(A) An SEA must collect and submit to MSIX the MDEs described in paragraph (b)(1)(i) of this section within 10 working days of approving a new Certificate of Eligibility for the migratory child. The SEA is not required to collect and submit MDEs in existence before its approval of a new Certificate of Eligibility for the child except as provided in paragraph (b)(3)(i)(B) of this section; and

(B) An SEA that approves a new Certificate of Eligibility for a secondary school-aged migratory child must also—

(*1*) Collect and submit to MSIX within 10 working days of approving a new Certificate of Eligibility for the child MDEs from the most recent secondary school in that State attended previously by the migratory child; and

(*2*) Notify MSIX within 30 calendar days if one of its local operating agencies obtains records from a secondary school attended previously in another State by the migratory child.

(ii) *End of term submissions.* (A) Within 30 calendar days of the end of an LEA's or local operating agency's fall, spring, summer, or intersession terms, an SEA must collect and submit to MSIX all MDE updates and newly available MDEs for migratory children who were eligible for the MEP during the term and for whom the SEA submitted data previously under paragraph (b)(2) or (b)(3)(i) of this section.

(B) When a migratory child's MEP eligibility expires before the end of a school year, an SEA must submit all MDE updates and newly available MDEs for the child through the end of the school year.

(iii) *Change of residence submissions.* (A) Within four working days of receiving notification from MSIX that a migratory child in its State has changed residence to a new local operating agency within the State or another SEA has approved a new Certificate of Eligibility for a migratory child, an SEA must collect and submit to MSIX all new MDEs and MDE updates that have become available to the SEA or one of its local operating agencies since the SEA's last submission of MDEs to MSIX for the child.

(B) An SEA or local operating agency that does not yet have a new MDE or MDE update for a migratory child when it receives a change of residence notification from MSIX must submit the MDE to MSIX within four working days of the date that the SEA or one of its local operating agencies obtains the MDE.

(c) *Use of Consolidated Student Records.* In order to facilitate school enrollment, grade and course placement, accrual of high school credits, and participation in the MEP, each SEA that receives a grant of MEP funds must—

(1) Use, and require each of its local operating agencies to use, the Consolidated Student Record for all migratory children who have changed residence to a new school district within the State or in another State;

(2) Encourage LEAs that are not local operating agencies receiving MEP funds to use the Consolidated Student Record for all migratory children described in paragraph (c)(1) of this section; and

(3) Establish procedures, develop and disseminate guidance, and provide training in the use of Consolidated Student Records to SEA, local operating agency, and LEA personnel who have been designated by the SEA as authorized MSIX users under paragraph (f)(2) of this section.

(d) *MSIX data quality.* Each SEA that receives a grant of MEP funds must—

(1) Use, and require each of its local operating agencies to use, reasonable and appropriate methods to ensure that all data submitted to MSIX are accurate and complete; and

(2) Respond promptly, and ensure that each of its local operating agencies responds promptly, to any request by the Department for information needed to meet the Department's responsibility for the accuracy and completeness of data in MSIX in accordance with the Privacy Act of 1974, as amended, 5 U.S.C. 552a(e)(6) and (g)(1)(C) or (D).

(e) *Procedures for MSIX data correction by parents, guardians, and migratory children.* Each SEA that receives a grant of MEP funds must establish and implement written procedures that allow a parent or guardian of a migratory child, or a migratory child, to ask the SEA to correct or determine the correctness of

MSIX data. An SEA's written procedures must meet the following minimum requirements:

(1) *Response to parents, guardians, and migratory children.* (i) Within 30 calendar days of receipt of a data correction request from a parent, guardian, or migratory child, an SEA must—

(A) Send a written or electronic acknowledgement to the requester;

(B) Investigate the request;

(C) Decide whether to revise the data as requested; and

(D) Send the requester a written or electronic notice of the SEA's decision.

(ii) If an SEA determines that data it submitted previously to MSIX should be corrected, the SEA must submit the revised data to MSIX within four working days of its decision to correct the data. An SEA is not required to notify MSIX if it decides not to revise the data as requested.

(iii)(A) If a parent, guardian, or migratory child requests that an SEA correct or determine the correctness of data that was submitted to MSIX by another SEA, within four working days of receipt of the request, the SEA must send the data correction request to the SEA that submitted the data to MSIX.

(B) An SEA that receives an MSIX data correction request from another SEA under this paragraph must respond as if it received the data correction request directly from the parent, guardian, or migratory child.

(2) *Response to SEAs.* An SEA or local operating agency that receives a request for information from an SEA that is responding to a parent's, guardian's, or migratory child's data correction request under paragraph (e)(1) of this section must respond in writing within ten working days of receipt of the request.

(3) *Response to the Department.* An SEA must respond in writing within ten working days to a request from the Department for information needed by the Department to respond to an individual's request to correct or amend a Consolidated Student Record under the Privacy Act of 1974, as amended, 5 U.S.C. 552a(d)(2) and 34 CFR 5b.7.

(f) *MSIX data protection.* Each SEA that receives a grant of MEP funds must—

(1) Enter into and carry out its responsibilities in accordance with an MSIX Interconnection Agreement, an MSIX Interconnection Security Agreement, and other information technology agreements required by the Secretary in accordance with applicable Federal requirements;

(2) Establish and implement written procedures to protect the integrity, security, and confidentiality of Consolidated Student Records, whether in electronic or print format, through appropriate administrative, technical, and physical safeguards established in accordance with the MSIX Interconnection Agreement and MSIX Interconnection Security Agreement. An SEA's written procedures must include, at a minimum, reasonable methods to ensure that—

(i) The SEA permits access to MSIX only by authorized users at the SEA, its local operating agencies, and LEAs in the State that are not local operating agencies but where a migratory child has enrolled; and

(ii) The SEA's authorized users obtain access to and use MSIX records solely for authorized purposes as described in paragraph (c) of this section;

(3) Require all authorized users to complete the User Application Form approved by the Secretary before providing them access to MSIX. An SEA may also develop its own documentation for approving user access to MSIX provided that it contains the same information as the User Application Form approved by the Secretary; and

(4) Retain the documentation required for approving user access to MSIX for three years after the date the SEA terminates the user's access.

Authority: 20 U.S.C. 6398.

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Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 1100, 1140, and 1143

Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1100, 1140, and 1143

[Docket No. FDA–2014–N–0189]

RIN 0910–AG38

Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing this final rule to deem products meeting the statutory definition of "tobacco product," except accessories of the newly deemed tobacco products, to be subject to the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). The Tobacco Control Act provides FDA authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, and any other tobacco products that the Agency by regulation deems to be subject to the law. With this final rule, FDA is extending the Agency's "tobacco product" authorities in the FD&C Act to all other categories of products that meet the statutory definition of "tobacco product" in the FD&C Act, except accessories of such newly deemed tobacco products. This final rule also prohibits the sale of "covered tobacco products" to individuals under the age of 18 and requires the display of health warnings on cigarette tobacco, roll-your own tobacco, and covered tobacco product packages and in advertisements. FDA is taking this action to reduce the death and disease from tobacco products. In accordance with the Tobacco Control Act, we consider and intend the extension of our authorities over tobacco products and the various requirements and prohibitions established by this rule to be severable.

DATES: This rule is effective August 8, 2016. See section IV of this document regarding compliance dates for certain provisions.

FOR FURTHER INFORMATION CONTACT: Gerie Voss or Katherine Collins, Office of Regulations, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 877–287–1373, *AskCTP@fda.hhs.gov.*

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Executive Summary

Purpose of the Rule

Cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco were immediately covered by FDA's tobacco product authorities in chapter IX of the FD&C Act (21 U.S.C. 387 through 387u) when the Tobacco Control Act went into effect. For other kinds of tobacco products, the statute authorizes FDA to issue regulations "deeming" them to be subject to such authorities. Consistent with the statute, once a tobacco product is deemed, FDA may put in place "restrictions on the sale and distribution of a tobacco product," including age-related access restrictions and advertising and promotion restrictions, if FDA determines the restrictions are appropriate for the protection of the public health. This final rule has two purposes: (1) To deem all products that meet the definition of "tobacco product" under the law, except accessories of a newly deemed tobacco product, and subject them to the tobacco control authorities in chapter IX of the FD&C Act and FDA's implementing regulations; and (2) to establish specific restrictions that are appropriate for the protection of the public health for the newly deemed tobacco products. In accordance with section 5 of the Tobacco Control Act, we consider and intend the extension of our authorities over tobacco products and the various requirements and prohibitions established by this rule to be severable.

FDA is taking this action to reduce the death and disease from tobacco products. Deeming all "tobacco products" (including components and parts but excluding accessories of the newly deemed products) to be subject to the FD&C Act will result in significant benefits for the public health. The final rule defines "component or part" and "accessory" to provide additional clarity as to which products are subject to FDA's tobacco product authority. With respect to these definitions, FDA notes that "component" and "part" are separate and distinct terms within chapter IX of the FD&C Act. However, for purposes of this final rule, FDA is using the terms "component" and "part" interchangeably and without emphasizing the distinction between the terms. FDA may clarify the distinctions between 'component' and 'part' in the future. Specifically, "Component or Part" means "any software or assembly of materials intended or reasonably expected: (1) To alter or affect the tobacco product's performance, composition, constituents or characteristics; or (2) to be used with or for the human consumption of a tobacco product. The term excludes anything that is an accessory of a tobacco product." Components and parts of the newly deemed tobacco products, but not their related accessories, are included in the scope of this final rule. The following is a nonexhaustive list of examples of components and parts used with electronic nicotine delivery systems (ENDS) (including e-cigarettes): E-liquids; atomizers; batteries (with or without variable voltage); cartomizers (atomizer plus replaceable fluid-filled cartridge); digital display/lights to adjust settings; clearomisers, tank systems, flavors, vials that contain e-liquids, and programmable software. Similarly, the following is a nonexhaustive list of examples of components and parts used with waterpipe tobacco: Flavor enhancers and the vials in which they are contained; hose cooling attachments; water filtration base additives (including those which are flavored); flavored waterpipe tobacco charcoals and the wrappers or boxes that contain the charcoals; and bowls, valves, hoses, and heads.

FDA is defining "accessory" to mean "any product that is intended or reasonably expected to be used with or for the human consumption of a tobacco product; does not contain tobacco and is not made or derived from tobacco; and meets either of the following: (1) Is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product or (2) is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a tobacco product but (i) solely controls moisture and/or temperature of a stored product or (ii) solely provides an external heat source to initiate but not maintain combustion of a tobacco product." Examples of accessories are ashtrays, spittoons, hookah tongs, cigar clips and stands and pipe pouches, because they do not contain tobacco, are not derived from tobacco, and do not affect or alter the performance, composition, constituents, or characteristics of a tobacco product. Examples of accessories also include humidors or refrigerators that solely control the moisture and/or temperature of a stored product and conventional matches and lighters that solely provide an external heat source to initiate but not maintain combustion of a tobacco product. An electric heater or charcoal used for prolonged heating of waterpipe tobacco is not an accessory because it is maintaining the combustion of the tobacco. Accessories of newly deemed tobacco products are not included within the scope of this final rule, although accessories of cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco remain subject to FDA's tobacco product authorities. FDA is not regulating accessories of newly deemed tobacco products because accessories, unlike components or parts, are expected to have little direct impact on the public health.

This final deeming rule affords FDA additional tools to reduce the number of illnesses and premature deaths associated with tobacco product use. For example, FDA will be able to obtain critical information regarding the health risks of newly deemed tobacco products, including information derived from ingredient listing submissions and reporting of harmful and potentially harmful constituents (HPHCs) required under the FD&C Act. As of the effective date, persons who own or operate a domestic establishment engaged in the manufacture, preparation, compounding, or processing of tobacco products (hereinafter, "manufacturing establishments") will be subject to the registration requirements. FDA will thus receive information on the location and number of manufacturing establishments, which will allow the Agency to establish effective compliance programs. In addition, this rule authorizes FDA to take enforcement action against manufacturers who sell and distribute products with unsubstantiated modified risk tobacco product (MRTP) claims, or false or misleading claims on their labeling or advertising, thus allowing for better-informed consumers and helping to prevent the use of misleading campaigns targeted to youth populations. It will also prevent from entering the market new tobacco products that are not appropriate for the protection of public health, are not substantially equivalent to a valid predicate product, or are not exempt from substantial equivalence (SE). Finally, the newly deemed tobacco products may be subject to future regulations that FDA determines are appropriate for the protection of public health.

Summary of the Major Provisions of the Regulatory Action

The final rule has two main sections: (1) Deeming provisions and (2) additional provisions to protect public health.

Deeming Provisions—After thorough review of the comments and the scientific evidence, FDA has concluded that Option 1 (including all cigars, rather than a subset) more effectively protects the public health and, therefore, has made that the scope of the final rule. Accordingly, this final rule deems all products meeting the statutory definition of "tobacco product," except accessories of the newly deemed tobacco products, to be subject to FDA's tobacco product authorities under chapter IX of the FD&C Act. Section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)), as amended by the Tobacco Control Act, defines the term "tobacco product," to mean "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)" and does not mean "an article that is a drug under subsection (g)(1), a device under subsection (h), or a combination product described in section 353(g) of this title."[1] Products that meet the statutory definition of "tobacco products" include currently marketed products such as dissolvables not already regulated by FDA, gels, waterpipe tobacco, ENDS (including e-cigarettes, e-hookah, e-cigars, vape pens, advanced refillable personal vaporizers, and electronic pipes), cigars, and pipe tobacco.

In addition, this final rule deems any additional current and future tobacco products that meet the statutory definition of "tobacco product," except accessories of such newly deemed products, to be subject to FDA's authorities under chapter IX of the FD&C Act. For example, FDA envisions that there could be tobacco products developed in the future that provide nicotine delivery through means (*e.g.,* via dermal absorption or intranasal spray) similar to currently marketed medicinal nicotine products, but which are not drugs or devices. These products would be "tobacco products" and subject to FDA's chapter IX authorities in accordance with this final deeming rule.

Upon the effective date of this final rule (*i.e.,* 90 days from the date of publication), the newly deemed products will be subject to the same FD&C Act provisions and relevant regulatory requirements to which cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco are subject, with respect to the following:

(1) Enforcement action against products determined to be adulterated or misbranded (other than enforcement actions based on lack of a marketing authorization during an applicable compliance period);

(2) Required submission of ingredient listing and reporting of HPHCs;

(3) Required registration of tobacco product manufacturing establishments and product listing;

(4) Prohibition against sale and distribution of products with modified risk descriptors (*e.g.,* "light," "low," and "mild" descriptors) and claims unless FDA issues an order authorizing their marketing;

(5) Prohibition on the distribution of free samples (same as cigarettes); and

(6) Premarket review requirements.

These actions will improve the public health by affording FDA critical information regarding the health risks of such products; preventing new products from entering the market unless such marketing is appropriate for the protection of public health, the products are found substantially equivalent to a valid predicate product, or the products are found exempt from the SE requirements; and preventing the use of unsubstantiated modified risk claims, which may mislead consumers and lead them to initiate tobacco product use or to continue using tobacco when they would otherwise quit.

Additional Provisions—In addition to the provisions in the FD&C Act and implementing regulations that apply automatically to the newly deemed products, FDA has the authority to invoke its other authorities under the Tobacco Control Act in regulating these products. At this time, under section 906(d) of the FD&C Act (21 U.S.C. 387f(d)), FDA is establishing three restrictions for covered tobacco products: (1) Requirement for a minimum age of purchase; (2) requirement for health warnings for product packages and advertisements (which FDA is also applying to cigarette tobacco and roll-your-own tobacco); and (3) prohibition of vending machine sales of such products, unless the vending machine is located in a facility where the retailer ensures that individuals under 18 years of age are prohibited from entering at any time. The term "covered tobacco products" is defined as those products deemed to be subject to the FD&C Act under section 1100.2 of title 21 of the Code of Federal Regulations (CFR), other than a component or part that is not made or derived from tobacco. We have slightly modified the definition of "covered tobacco products" from the notice of proposed rulemaking (NPRM) to clarify that components or parts that are "covered tobacco products" include not only those that contain tobacco or nicotine, but also those that contain any tobacco derivative (*i.e.,* we have changed the NPRM definition, which excluded "any component or part of a tobacco product that does not contain nicotine or tobacco," to exclude "any component or part of a tobacco product that is not made or derived from tobacco" as stated in this final rule).

Effective Dates—The deeming provisions (*i.e.,* those provisions that automatically apply to newly deemed products) and minimum age and identification and vending machine restrictions are effective 90 days from the date of publication of the final rule. The health warning requirements are effective 24 months from the date of publication of the final rule, with an additional 30-day period in which a manufacturer may continue to introduce into interstate commerce existing inventory manufactured before the effective date that does not contain the required warning statements on packaging.

This means that:

- After the effective date, no manufacturer, packager, importer, distributor, or retailer of cigarette tobacco, roll-your-own tobacco, cigars, or other covered tobacco products may advertise any such product if the advertisement does not comply with this rule;
- After the effective date, no person may manufacture for sale or distribution within the United States any such product the package of which does not comply with this rule;
- Beginning 30 days after the effective date, a manufacturer may not introduce into domestic commerce, any such product, irrespective of the date of manufacture, if its package does not comply with this rule (*i.e.,* non-compliant products manufactured prior to the effective date may not be

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[1] FDA notes that some products falling within the FD&C Act's definition of "tobacco product" may not be considered tobacco products for Federal excise tax purposes (see 26 U.S.C. 5702(c)). Taxation of tobacco products, as defined by the Internal Revenue Code, falls under the jurisdiction of the U.S. Department of the Treasury/Alcohol and Tobacco Tax and Trade Bureau (TTB). Neither FDA's act of "deeming" nor any other FDA regulations directly affect the taxation of any tobacco product.

distributed for retail sale after 30 days following the effective date);

- After the effective date, a distributor or retailer may not sell, offer to sell, distribute, or import for sale or distribution within the United States any such product the package of which does not comply with this regulation, unless the covered tobacco product was manufactured prior to the effective date; and
- After the effective date, however, a retailer may sell covered tobacco products in packages that do not have a required warning if the retailer demonstrates it falls outside the scope of this rule as described in 21 CFR 1143.3(a)(3) and 1143.5(a)(4).

Compliance Policy for Premarket Review—Manufacturers of newly deemed products that are "new tobacco products" as defined in section 910(a)(1) of the FD&C Act will be required to obtain premarket authorization of their products through one of three pathways—SE., exemption from SE., or premarket tobacco product applications (sections 905 and 910 of the FD&C Act). As stated in the NPRM, we understand that, for some newly deemed tobacco products, particularly novel products, there may not be appropriate predicate products that were on the market on February 15, 2007, to support a SE claim. Accordingly, in the NPRM, FDA contemplated a compliance period of 24 months after the effective date of the final rule for the submission of applications for all newly deemed, new tobacco products under all three marketing pathways—premarket tobacco applications (PMTAs), SE reports, and SE exemption requests.[2]

FDA carefully considered numerous comments regarding the contemplated compliance period. Many comments expressed concern that newly deemed, new tobacco products would remain available and could continue to be marketed indefinitely without scientific review. Other comments expressed concern, and some submitted data, regarding the effect that flavors have on youth and young adult use of tobacco products. FDA also received comments and data regarding the potential for some net public health benefits that could accrue if flavored ENDS remain available. After carefully considering all of these comments, FDA here announces a revised compliance policy as well as the final rule. (Agency compliance/enforcement policies are not subject to the requirements that govern notice-and-comment rulemaking. *Prof'ls & Patients for Customized Care* v. *Shalala,* 56 F.3d 592 (5th Cir. 1995) (a compliance policy guide is not a substantive rule and not subject to the Administrative Procedure Act's (APA) notice-and-comment rulemaking); *Takhar* v. *Kessler,* 76 F.3d 995, 1002 (9th Cir. 1996) (FDA compliance policy guides were not required to go through notice-and-comment procedures). But because the relevant time periods are of obvious interest, FDA laid out its anticipated compliance policy in the NPRM, and for similar reasons, is announcing its revised compliance policy here, rather than in a separate guidance document.) As a result of FDA's compliance policy, we expect that many manufacturers will keep their products on the market beyond the effective date of this final rule. However, if a manufacturer of a product is unable to support an SE claim for its product (*e.g.,* is unable to identify a valid predicate, or does not submit an SE report with a valid predicate within the compliance period, or does not receive authorization within a continued compliance period) and does not obtain authorization under one of the other available marketing pathways before the end of an applicable compliance period, such products remaining on the market will be subject to enforcement (*e.g.,* seizure, injunction) for failure to have a marketing authorization under sections 905 and 910 of the FD&C Act.

FDA's NPRM included detailed requests for comments on different possible compliance policy approaches. 79 FR at 23175–77. FDA received many comments on these compliance-policy issues. For example, comments jointly submitted by 24 health and medical organizations stated that the contemplated 24-month compliance period and indefinite period of continued marketing during FDA review included in the NPRM would prolong the public's exposure to products that contain nicotine, a highly addictive substance, and that do not meet the statutory standard for the grant of a marketing order (Comment No. FDA–2014–N–0189–79772.). They stated that this approach would allow manufacturers to market the newly deemed products in ways that appeal to youth and to manipulate the content of these products in uncontrolled ways for an indefinite period (id.). Ranking minority members of the Energy and Commerce Committee, Health Subcommittee, and Oversight and Investigations Subcommittee, U.S. House of Representatives also called for a more protective compliance period than the one contemplated in the NPRM, arguing that the proposed compliance period "puts the nation's youth at risk" (Comment No. FDA–2014–N–0189–80119). Further, a network of tobacco control policy and legal specialists expressed concern regarding the effect of continued marketing of tobacco products that have not been reviewed under the applicable public health standards of the Tobacco Control Act (Comment No. FDA–2014–N–0189–81044). FDA also received comments suggesting that the agency should stagger the compliance periods for different product classes based on the continuum of risk, with ENDS having a longer compliance period than other product classes (*e.g.,* Comment No. FDA–2014–N–0189–81859; Comment No. FDA–2014–N–0189–10852). FDA also received comments and new data regarding the effect of flavored tobacco products on youth and young adult use.

FDA understands that the appeal of flavors and use of flavored tobacco products have an important role in the initiation and continued use of tobacco products, and in the health risks associated with use of these products. Based on all of these comments, we have determined that exercising enforcement discretion indefinitely could put youth and young adults at risk for tobacco-related death and disease. However, we recognize that the availability of alternatives to traditional tobacco flavors in some products (*e.g.,* ENDS) may potentially help some adult users who are attempting to transition away from combusted products. Furthermore, at least some flavored combusted products are likely to be "grandfathered" and therefore would remain on the market regardless of the compliance period provided in the preamble. Taking into consideration all of the comments on the compliance period and flavors, we are establishing staggered compliance periods. This approach will enable FDA to balance concerns regarding the extended availability of all newly deemed, new tobacco products without scientific review, concerns regarding flavored tobacco products' appeal to youth, and emerging evidence that some adults may potentially use certain flavored tobacco products to transition away from combusted tobacco use. FDA is establishing staggered initial compliance periods based on the expected complexity of the applications to be submitted, followed by continued compliance periods for FDA review such that our exercise of enforcement discretion will end twelve months after each initial compliance period. In other words, manufacturers of all newly deemed, new tobacco products will have a 12-, 18- or 24-month initial compliance period in which to prepare applications for marketing authorization, as well as a 12-month continued compliance period after those dates in which to obtain authorization from FDA (resulting in total compliance periods of 24, 30, or 36 months). After the close of the continued compliance period, products will be subject to enforcement unless they are grandfathered or are the subject of a marketing authorization order. FDA's revised compliance policy for premarket review—resulting in products remaining on the market while manufacturers seek review but also contemplating an end to the continued compliance policy—will balance the public health concerns raised in the comments, allow the Agency to more efficiently manage the flow of incoming applications, and encourage high-quality premarket submissions from applicants.

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[2] Although the NPRM did not explicitly include SE exemption requests as one of the marketing pathways that applicants could utilize within a compliance period, FDA did intend for its contemplated 24-month compliance period to be available for all marketing pathways.

According to this revised compliance policy, for newly deemed products that are on the market on the effective date of this final rule and were not on the market on February 15, 2007, FDA is providing a 12-month initial compliance period for manufacturers to submit (and FDA to receive) an SE exemption request, an 18-month initial compliance period for manufacturers to submit (and FDA to receive) SE applications, and a 24-month initial compliance period for manufacturers to submit (and FDA to receive) a PMTA.

If manufacturers submit (and FDA receives) the applications during their respective compliance periods, FDA, for a certain period of time as discussed in the following paragraph, intends to continue the compliance policy and does not intend to initiate enforcement action for these products remaining on the market without FDA authorization.

For newly deemed tobacco products using the SE Exemption pathway, this continued compliance period (*i.e.*, the time during which FDA does not intend to enforce the premarket review requirements) will close 24 months after the effective date of part 1100 of this final deeming rule (*i.e.*,12 months after the 12-month initial compliance period closes for submission and receipt of SE exemption requests). The earlier submission period for the SE exemption pathway is intended to allow the manufacturer time to consider other pathways if the exemption request is denied or if FDA refuses to accept the request if, for example, the application is incomplete. For newly deemed tobacco products using the SE pathway, this continued compliance period will close 30 months after the effective date of part 1100 of this final deeming rule (*i.e.*, 12 months after the 18-month initial compliance period closes for submission and receipt of SE Reports). For newly deemed tobacco products using the PMTA pathway, this continued compliance period will close 36 months after the effective date (*i.e.*, 12 months after the 24-month compliance period closes for submission and receipt of PMTAs). Any such newly deemed tobacco product for which an application under one of the three marketing pathways has not been submitted within 24 months from the effective date of part 1100 of this final deeming rule will not benefit from this continued compliance policy and will be subject to enforcement as of that date. In addition, once the respective continued compliance period ends for products with applications submitted according to this policy, products remaining on the market without premarket authorizations in effect, even if the product has a pending application that was originally submitted by its respective initial compliance deadline set forth previously in this document, will be subject to enforcement. However, if at the time of the conclusion of the continued compliance period, the applicant has provided the needed information and review of a pending marketing application has made substantial progress toward completion, FDA may consider, on a case-by-case basis, whether to defer enforcement of the premarket authorization requirements for a reasonable time period.

Regarding concerns as to the inability to use the SE pathway for certain products, FDA notes that an applicant may use as a predicate any tobacco product commercially marketed in the United States as of February 15, 2007, or previously found substantially equivalent (note that we interpret the phrase "as of" February 15, 2007, as meaning that the tobacco product was commercially marketed (other than exclusively in test markets) in the United States on February 15, 2007. If your tobacco product had been commercially marketed in the United States before February 15, 2007, but was not commercially marketed on that date, it is not a grandfathered product and may not be commercially marketed unless you obtain a marketing authorization under section 910 of the FD&C Act).[3] This may possibly include a predicate that is in a different category or subcategory than the new product that is the subject of the SE report. While FDA currently does not have a policy that limits comparisons to the same category, we do see cross-category comparisons as more challenging for an applicant and we may express limitations on such comparisons in the future, if they become warranted as we gain experience regulating newly deemed products. FDA also is continuing to research e-cigarettes, other ENDS, and heated cigarette products that likely were on the market "as of" (*i.e.*, on) February 15, 2007. Additionally, FDA has determined that some e-cigarettes and other ENDS were manufactured in 2006 and commercially marketed in the United States in early 2007. In particular, we have identified an ENDS product that may have been on the market on February 15, 2007. This product may possibly be able to serve as a valid predicate for purposes of the SE pathway. The burden of demonstrating that a valid predicate exists rests with the manufacturer submitting a SE report. To facilitate the determination that a product is eligible to serve as a valid predicate, any individual who has evidence that an e-cigarette or other ENDS was commercially marketed in the United States on February 15, 2007, may submit a stand-alone grandfather submission to FDA (See final guidance, "Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007" (79 FR 58358, September 29, 2014)). (Based on FDA's experiences to date, and since stand-alone grandfather submissions are purely voluntary, FDA does not anticipate that many manufacturers will make such submissions, but this option is available.) Regardless of the predicate selected for comparison, manufacturers are responsible for providing scientific data adequate to demonstrate that, in the case of an SE report, the characteristics of the new product are the same as the predicate or, if the characteristics are different, that these differences do not cause the new product to raise different questions of public health. We encourage interested parties to review the applications FDA posts on *http://www.fda.gov* for examples of products that do not raise different questions of public health when compared with the specified predicate product.

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[3] FDA Guidance states that "[i]f you cannot provide documentation specifically dated on February 15, 2007, FDA suggests you provide documentation of commercial marketing for a reasonable period of time before and after February 15, 2007." Guidance for Industry entitled "Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007 (79 FR 58358, Sept. 29, 2014). The guidance also provides examples of sources of evidence, *e.g.*, bills of lading.

Vape Establishments Acting as Manufacturers—Several comments asked FDA to clarify whether e-cigarette retail stores and vape establishments are considered "tobacco product manufacturers" under the FD&C Act. In response, FDA has explained that establishments that mix or prepare e-liquids or create or modify aerosolizing apparatus for direct sale to consumers are tobacco product manufacturers under the definition set forth in the FD&C Act and, accordingly, are subject to the same legal requirements that apply to other tobacco product manufacturers.

Revisions to Health Warning Requirements—FDA is finalizing this deeming rule with a few changes to the proposed health warning requirements for newly deemed products. For example, FDA has slightly revised the nicotine warning statement to read: "WARNING: This product contains nicotine. Nicotine is an addictive chemical." The alternative warning statement for products that do not contain nicotine (*i.e.,* no nicotine at detectable levels) is revised to read: "This product is made from tobacco." We have also provided additional language explaining the process for self-certifying that the product does not contain nicotine, which must be submitted to FDA, and the recordkeeping recommendations for this self-certification. E-liquids that do not contain tobacco or nicotine or are not derived from tobacco or nicotine do not meet the definition of "covered tobacco product," as described throughout this final rule, and will not be required to carry an addiction warning or to submit a self-certification. In addition, we have added language to clarify that the warning statements on packages must be printed in at least 12-point font size to be conspicuous and legible.

Further, we have added a provision to indicate that a product package too small or otherwise unable to accommodate a label with sufficient space to bear such information will be exempt from the requirements to place the warning statement directly on packages (as required in § 1143.3(a)(1)), as long as the warning requirements enumerated in § 1143.3(a)(2) and (d) are met. For instance, for small packages, the warning statement must appear on the two principal display panels on the outer carton or other outer container or wrapper or on a tag otherwise permanently affixed to the tobacco product package. This required warning must be printed using the same specifications in § 1143.3(a)(1) and (2) (which provide the specifications for the addiction warning). In such cases, the carton, outer container, wrapper, or tag would serve as one of the principal display panels.

Reproductive Health Warning for Cigars—In the proposed deeming rule, FDA proposed to require four of the five warnings already included on most cigar packages and in most cigar advertisements as a result of settlement agreements between the Federal Trade Commission (FTC) and the seven largest U.S. cigar manufacturers (hereinafter, "FTC consent decrees"). (See, *e.g.,* In re Swisher International, Inc., Docket No. C–3964.) FDA did not propose to require the fifth warning (SURGEON GENERAL WARNING: Tobacco Use Increases the Risk of Infertility, Stillbirth and Low Birth Weight), but asked for comments regarding this decision. Upon further consideration, FDA has decided to require a fifth warning regarding reproductive health effects and cigar use specifically, which reads "WARNING: Cigar use while pregnant can harm you and your baby." This requirement is supported by existing scientific evidence and is appropriate for the protection of the public health. However, because the general statement "Tobacco smoke increases the risk of infertility, stillbirth and low birth weight" is also a true statement, and because scientific evidence demonstrates that cigar smoke is similar in content and effects to cigarette smoke, FDA is allowing the use of the reproductive health warning required by the FTC consent decrees as an optional alternative to the fifth FDA warning. FDA expects that providing the optional alternative will benefit entities bound by the FTC consent decrees.

Nicotine Exposure Warning and Child-Resistant Packaging—After reviewing the comments, FDA recognizes the importance of alerting consumers to, and protecting children from, the hazards from ingestion of, and eye and skin exposure to, e-liquids containing nicotine. Toward that end, FDA issued an advance NPRM (ANPRM) prior to this deeming rule (80 FR 51146 (2015)), seeking comments, data, research, or other information that may inform regulatory actions FDA may take with respect to a nicotine exposure warning and child-resistant packaging. In addition, elsewhere in this issue of the **Federal Register**, FDA has made available draft guidance, which when final will describe FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products, including recommendations for exposure warnings and child-resistant packaging that would help to support a showing that the marketing of a product is appropriate for the protection of public health.

Requests for Additional Regulations Applicable to Newly Deemed Products—In the NPRM, FDA noted that, once the products were deemed, the Agency could issue additional regulations applicable to newly deemed products, including product standards under section 907 of the FD&C Act (21 U.S.C. 387g). FDA received many suggestions for additional regulations that should apply to the newly deemed products. FDA is taking these comments under advisement and considering whether to issue NPRMs for such provisions.

Compliance Policy Regarding Certain Provisions and Small-Scale Tobacco Product Manufacturers—In the NPRM, FDA requested comment on the ability of small manufacturers of newly deemed tobacco products to fully comply with the requirements of the FD&C Act and how FDA might be able to address those concerns. Considering the comments and FDA's finite enforcement resources, the Agency's view is that those resources may not be best used in immediately enforcing certain provisions of this rule against certain manufacturers that are small-scale tobacco product manufacturers and that may need additional time to comply with certain requirements of the FD&C Act. Generally, for purposes of this new compliance policy in which FDA is specifying additional periods of time for such manufacturers to comply with certain provisions (*i.e.,* additional time to respond to SE deficiency letters, an additional six-month compliance period for the tobacco health document submission requirements, and additional time to submit ingredient listings, as discussed in Section IV.D). As with manufacturers generally, these small-scale tobacco manufacturers will also benefit from additional assistance with their marketing applications, including: a Regulatory Health Project Manager so that they have a single point of contact in FDA's Center for Tobacco Products (CTP's) Office of Science (OS) for questions about their marketing applications; an appeals process for denial of marketing applications (of which one small business has already taken advantage); and staff from CTP's Office of Compliance and Enforcement (OCE), who assist such businesses in helping them to identify documents that may be used to establish that their predicate products were on the market on February 15, 2007. Further, CTP's OCE will continue to assist small-scale tobacco product manufacturers in their submission of rotational warning plans for FDA approval and to provide a system to assist such businesses in navigating the regulatory requirements of FDA. FDA considers a "small-scale tobacco product manufacturer" to be a manufacturer of any regulated tobacco product that employs 150 or fewer full-time equivalent employees and has annual total revenues of $5,000,000 or less. In formulating our thinking on what a small-scale tobacco product manufacturer is for purposes of this policy, FDA has considered all available data on employment, revenues, production volume and other details of operation for current manufacturers of newly deemed products. FDA considers a manufacturer to include each entity that it controls, is controlled by, or is under common control with. To help make FDA's individual enforcement decisions more efficient, a manufacturer may voluntarily submit information regarding employment and revenues.[4]

Policy for Certain Regulatory Requirements for All Manufacturers of Newly Deemed Products—Although FDA maintains that all of the automatic provisions are important given that all tobacco products have inherent risks, FDA recognizes that compliance with many of the automatic provisions may be challenging at first for entities that are new to Federal public health regulation. In addition, FDA expects that it will obtain necessary information from its regulation of finished tobacco products. As a result, FDA has established a compliance policy for premarket submission and for obtaining authorization with respect to certain components and parts of newly deemed tobacco products. We note that FDA also intends to issue a guidance regarding HPHC reporting under section 904(a)(3), and later a testing and reporting regulation as required by section 915, with enough time for manufacturers to report given the 3-year compliance period for HPHC reporting. Section 904(a)(3) requires the submission of a report listing all constituents, including smoke constituents identified as harmful or potentially harmful (HPHC) by the Secretary. Section 915 requires the testing and reporting of the constituents, ingredients, and additives the Secretary determines should be tested to protect the public health. The section 915 testing and reporting requirements apply only after FDA issues a regulation implementing that section, which it has not yet done. Until these testing and reporting requirements have been established, newly deemed tobacco products (and currently regulated tobacco products) are not subject to the testing and reporting provisions found under section 915. As noted elsewhere in this document, FDA does not intend to enforce the reporting requirements under section 904(a)(3) for newly deemed products before the close of the 3-year compliance period, even if the HPHC guidance and the section 915 regulation are issued well in advance of that time.

Severability—In accordance with section 5 of the Tobacco Control Act, FDA considers and intends the extension of its authorities over all tobacco products and the various requirements and prohibitions established by this rule to be severable. It is FDA's interpretation and position that the invalidity of any provision of this rule shall not affect the validity of any other part of this rule. In the event any court or other lawful authority were to temporarily or permanently invalidate, restrain, enjoin, or suspend any provision of this final rule, FDA would conclude that the remaining parts continue to be valid. As stated in section 5 of the Tobacco Control Act, if certain applications of this rule to persons or circumstances (discussed in the preamble or otherwise) are held to be invalid, application of such provisions to any other person or circumstance will not be affected and will continue to be enforced. Each provision of the rule is independently supported by data and analysis as described or referenced in this preamble and, if issued separately, would remain a proper exercise of FDA authority.

Costs and Benefits

This final rule deems all products meeting the statutory definition of "tobacco product," except accessories of a newly deemed tobacco product, to be subject to chapter IX of the FD&C Act. This final rule also finalizes additional provisions that would apply to certain newly deemed products as well as to certain other tobacco products. Once deemed, tobacco products become subject to the FD&C Act and its implementing regulations. The FD&C Act requirements that will apply to newly deemed products include establishment registration and product listing, ingredient listing, HPHC testing and reporting, premarket submissions prior to the introduction of new products, and labeling requirements. Free samples of newly deemed tobacco products will also be prohibited. The additional provisions of this final rule include minimum age and identification requirements, vending machine restrictions, and required warning statements for packages and advertisements.

TABLE 1—SUMMARY OF QUANTIFIED COSTS OVER 20 YEARS

[$ million]

	Lower bound (3%)	Primary (3%)	Upper bound (3%)	Lower bound (7%)	Primary (7%)	Upper bound (7%)
Present Value of Private Sector Costs	517.7	783.7	1,109.8	450.4	670.9	939.8
Present Value of Government Costs[1]	204.6	204.6	204.6	145.7	145.7	145.7
Present Value of Total Costs	722.3	988.2	1,314.4	596.1	816.5	1,085.4
Annualized Value of Private Sector Costs	34.8	52.7	74.6	42.5	63.3	88.7
Annualized Value of Government Costs[1]	13.8	13.8	13.8	13.8	13.8	13.8
Annualized Value of Total Costs	48.5	66.4	88.3	56.3	77.1	102.5

[1] FDA costs represent an opportunity cost, but this rule will not result in changes to overall FDA accounting costs, the size of the Federal budget, or the total amount of tobacco industry user fees.

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[4] FDA notes that our current thinking regarding "small-scale tobacco product manufacturer" for purposes of this compliance policy differs from definitions of "small manufacturer" or "small tobacco product manufacturer" that pertain in several other contexts, including definitions established by the Small Business Administration or the Tobacco Control Act's definition of a "small tobacco product manufacturer." FDA notes that its current thinking reflects an evaluation of all available data regarding manufacturers of newly deemed tobacco products, as well as careful review of the potentially unique interests of the smallest tobacco product manufacturers as considered in light of the Agency's statutory obligations regarding the protection of public health.

The direct benefits of making each of the newly deemed tobacco products subject to the requirements of chapter IX of the FD&C Act are difficult to quantify, and we cannot predict the size of these benefits at this time. Table 1 summarizes the quantified costs of this final rule over 20 years. For the reasons provided in the preamble and analysis of impacts, FDA has concluded that the benefits of the final rule justify the costs. Among other effects, new products will be subject to an evaluation to ensure they meet the appropriate public health standard for the pathway before they can be marketed, labeling cannot contain misleading statements, and FDA will be made aware of the ingredients in newly deemed tobacco products. If, without the final rule, new products would pose substantially greater health risks than those already on the market, the premarket requirements made effective by this final rule would keep such products from appearing on the market and worsening the health effects of tobacco product use. The warning statements required by this final rule will help consumers better understand and appreciate the risks and characteristics of tobacco products.

I. Background

Cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco were immediately covered by FDA's tobacco product authorities in chapter IX of the FD&C when the Tobacco Control Act went into effect. For other tobacco products, the statute authorized FDA to issue regulations "deeming" them to be subject to such authorities. Consistent with the statute, once a tobacco product is deemed, FDA may put in place "restrictions on the sale and distribution of a tobacco product," if FDA determines the restrictions are appropriate for the protection of the public health (21 U.S.C. 387f(d)(1)).

The Surgeon General has long recognized that the addictive nature of tobacco products is due to the presence of highly addictive nicotine that can be absorbed into the bloodstream (see, *e.g.*, Ref. 1 at 6–9). While the amount of nicotine delivered and the means through which it is delivered can either reduce or enhance nicotine's potential for abuse and physiological effects (Ref. 2 at 113), nicotine is addictive. In general, the quicker the delivery, rate of absorption, and attainment of peak concentrations of nicotine, the greater the potential for addiction (id.).

The Surgeon General reported that "most people begin to smoke in adolescence and develop characteristic patterns of nicotine dependence before adulthood" (Ref. 3). These youth develop physical dependence and experience withdrawal symptoms when they try to quit smoking (id.). As a result, addiction to nicotine is often lifelong (Ref. 4), and youth and young adults generally "underestimate the tenacity of nicotine addiction and overestimate their ability to stop smoking when they choose" (Ref. 5). For example, in a study of over 1,200 sixth grade students who inhaled tobacco products, 58.5 percent had lost autonomy over their tobacco use (*i.e.*, had difficulty trying to quit) (Ref. 6). One survey also revealed that "nearly 60 percent of adolescents believed that they could smoke for a few years and then quit" (Ref. 7). Research conducted in animal models has indicated that exposure to substances such as nicotine can disrupt prenatal brain development and may have long-term consequences on executive cognitive function and on the risk of developing a substance abuse disorder and various mental health problems as an adult (Ref. 8), and this exposure to nicotine can also have long-term results on decreasing attention performance and increasing impulsivity which could promote the maintenance of nicotine use behavior (id.).

The Surgeon General also emphasizes that "nicotine addiction develops as a neurobiologic adaptation to chronic nicotine exposure," suggesting that the pattern of tobacco product use (*e.g.*, frequency of using the product) is a factor in the facilitation of nicotine addiction (Ref. 9 at 112). The Surgeon General also noted "all forms of nicotine delivery do not pose an equal risk in establishing and maintaining addiction" and this may be because the pharmacokinetics of various nicotine containing products differ (id.). The FDA-approved nicotine patch is an example of slow absorption and once-a-day dosing which results in minimal potential for addiction (Ref. 2 at 113). In 1988, the Surgeon General recognized that the ultimate levels of nicotine absorbed into the blood from tobacco products on the market at that time can be similar in magnitude regardless of the product forms used to deliver nicotine (Ref. 1). For example, research has shown that oral use of smokeless tobacco products that do not emit smoke results in "high venous concentrations of nicotine equal to those for use of cigarettes" (Ref. 2 at 113).

FDA believes that the inhalation of nicotine (*i.e.*, nicotine without the products of combustion) is of less risk to the user than the inhalation of nicotine delivered by smoke from combusted tobacco products. However, limited data suggest that the pharmacokinetic properties of inhaled nicotine can be similar to nicotine delivered by combusted tobacco products. Thus, inhaled nicotine from a non-combustible product may be as addictive as inhaled nicotine delivered by combusted tobacco products. Researchers recognize that the effects from nicotine exposure by inhalation without combustion are likely not responsible for the high prevalence of tobacco-related death and disease in this country (Refs. 10, 11). Although nicotine itself has not been shown to cause the chronic disease associated with tobacco use, the 2014 Surgeon General's report noted that there are still risks associated with nicotine (Ref. 9 at 111). For example, nicotine at high enough doses has acute toxicity (id.). Research in animal models have demonstrated that nicotine exposure during fetal development may have lasting adverse consequences for brain development (id.). Nicotine also adversely affects maternal and fetal health during pregnancy, contributing to multiple adverse outcomes such as preterm delivery and stillbirth (id.; citing Refs. 12, 13). Further, data from studies of mice also suggest that nicotine exposure during adolescence may have lasting adverse consequences for brain development (id.). Some studies in animal models also have found that nicotine can have detrimental effects on the cardiovascular system and potentially disrupt the central nervous system (Refs. 14, 15).

"Since the 1964 Surgeon General's report, comprehensive tobacco control programs and policies have been proven effective for controlling tobacco use" (Ref. 9 at 36). Accordingly, FDA is issuing this final rule to serve two purposes: (1) To deem products that meet the definition of "tobacco product" under the law, except accessories of newly deemed tobacco products, and subject them to the tobacco control authorities in the FD&C Act; and (2) to establish specific restrictions that are appropriate for the protection of the public health for the newly deemed tobacco products. To satisfy these purposes, FDA proposed two options (Option 1 and Option 2), which provided two alternatives for the scope of the deeming provisions and, consequently, the application of the additional specific provisions. Under Option 1, all products meeting the definition of a "tobacco product," except accessories of newly deemed tobacco products, would be deemed. Option 2 was the same as Option 1, except a subset of cigars known as "premium cigars" would be excluded.

Currently, tobacco products unregulated by FDA are widely available and come in many forms, including cigars, pipe tobacco, waterpipe tobacco, liquids (e-liquids) for ENDS (the most popular of which are electronic cigarettes, but also include e-hookah, e-cigars, vape pens, personal vaporizers, and electronic pipes), liquid nicotine that is made or derived from tobacco, nicotine gels, and certain dissolvable tobacco products (*i.e.*, dissolvable products that do not currently meet the definition of "smokeless tobacco" in section 900(18) of the FD&C Act (21 U.S.C. 387(18)) because they do not contain cut, ground, powdered, or leaf tobacco and instead contain nicotine extracted from tobacco). Upon implementation of this final rule, currently unregulated tobacco products and future products meeting the definition of "tobacco product" under section 201(rr) (except accessories of newly deemed tobacco products) will be subject to chapter IX of the FD&C Act.

FDA issued a proposed deeming rule on April 25, 2014 (79 FR 23142). We received over 135,000 comments on the NPRM. Comments were received from tobacco product manufacturers, retailers, academia, medical professionals, local governments, advocacy groups, and consumers. To make it easier to identify comments and our responses, the word "Comment," in parentheses, will appear before each comment, and the word "Response," in parentheses, will appear before each response. We have numbered the comments to make it easier to distinguish between comments; the numbers are for organizational purposes only and do not reflect the order in which we received the comments or any value associated with them. We have combined similar comments under one numbered comment. In addition to the comments specific to this rulemaking that we address in the following paragraphs, we received many general comments expressing support or opposition to the rule and separate provisions within the rule. These comments express broad policy views and do not address specific points related to this rulemaking. Therefore, these general comments do not require a response. Other comments outside the scope of this rulemaking also have not been addressed here. The remaining comments, as well as FDA's responses, are included in this document.

II. Legal Authority

A. Summary of Legal Authority

As set forth in the preamble to the NPRM (79 FR 23142 at 23145), the Tobacco Control Act provided FDA with the authority to regulate tobacco products by, among other things, adding chapter IX to the FD&C Act. Section 901 of the FD&C Act (21 U.S.C. 387a) provides that this new chapter (Chapter IX—Tobacco Products) applies to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary of Health and Human Services by regulation deems to be subject to this chapter. In accordance with section 901 of the FD&C Act, FDA issued a NPRM to extend FDA's "tobacco product" authorities to products that meet the statutory definition of "tobacco product" in section 201(rr) of the FD&C Act,[5] except the accessories of these tobacco products, and provided two separate options as to the scope of cigar products that would be deemed subject to FDA's tobacco authorities. FDA is selecting Option 1 deeming all tobacco products, including premium cigars, except the accessories of the newly deemed products, with this final rule.

In addition, section 906(d)(1) of the FD&C Act authorizes FDA to require restrictions on the sale and distribution of a tobacco product, if the Agency determines that "such regulation would be appropriate for the protection of the public health." FDA has determined that the additional restrictions included with this final rule (*i.e.*, minimum age and identification requirements, vending machine restrictions, and health warning statements) are "appropriate for the protection of the public health."

These authorities are supplemented by section 903 of the FD&C Act (21 U.S.C. 387c), which provides, among other things, that a tobacco product is misbranded unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that tobacco product a brief statement of the uses of the tobacco product and relevant warnings, precautions, side effects, and contraindications (section 903(a)(8)(B)(i) of the FD&C Act). Section 903(a)(7)(B) of the FD&C Act also provides that a tobacco product is misbranded if it is sold or distributed in violation of a regulation prescribed under section 906(d) of the FD&C Act.

In addition, section 701(a) of the FD&C Act (21 U.S.C. 371(a)) provides FDA with authority to issue regulations for the efficient enforcement of the FD&C Act.

B. Responses to Comments Regarding Legal Authority

FDA received comments on a wide range of legal issues, including FDA's authority to deem tobacco products subject to the FD&C Act and constitutional issues that may be implicated by the NPRM. FDA carefully considered these comments and concludes that the Agency has authority to deem the tobacco products covered under this final rule. FDA is not aware of other legal concerns from comments that prevent the Agency from taking the actions included in this final rule. A summary of comments regarding legal authority, and FDA's responses, follows.

1. Section 901 Authority

(Comment 1) Generally, the comments did not challenge FDA's authority under section 901 of the FD&C Act, but at least one comment argued that section 901 does not grant FDA the authority to deem, "in a sweeping manner," all products (excluding accessories) that meet the statutory definition of "tobacco product." The comment argued that Congress intended to grant FDA discretion to deem products only on a product-by-product basis, or at best, a category-by-category basis, and that FDA lacks authority to "simply swallow all extant and future tobacco products up in its authority[.]"

(Response) FDA disagrees. Section 901 grants FDA the authority to deem "any . . . tobacco products that the Secretary by regulation deems to be subject to [chapter IX of the FD&C Act]." There is no provision in the statute that restricts FDA's authority to deem all tobacco products that meet the statutory definition or requires FDA to deem products on an individual or product category basis.

The comment did not provide a basis for the claim that Congress intended to restrict FDA's deeming authority to piecemeal deeming of specific categories of products and no such restrictions exist. FDA believes that deeming tobacco products on a product or category basis would create regulatory loopholes, substantial delay (at the risk to public health), and significantly impede FDA's ability to create a comprehensive regulatory scheme.

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[5] Section 201(rr) of the FD&C Act defines "tobacco product," in relevant part, as any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). 21 U.S.C. 321(rr).

Even if there was ambiguity in the wording of section 901, which FDA does not believe there is, FDA would be entitled to deference on this interpretation of the statute (*Chevron U.S.A., Inc.* v. *Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842–45 (1984), quoting *Morton* v. *Ruiz*, 415 U.S. 199, 231 (1974) ("We have long recognized that considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer, and the principle of deference to administrative interpretations . . .")).

(Comment 2) At least one comment questioned whether section 901 of the FD&C Act provides authority to deem future tobacco products under the new rule. Specifically, the comment argued that a "tobacco product" must exist at the time the rule takes effect for it to be subject to "deeming" under the rule.

(Response) FDA disagrees. The term "tobacco product" is defined in section 201(rr) of the FD&C Act, 21 U.S.C. 321(rr), to mean "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)," and excluding drugs, devices, and combination products as defined under the FD&C Act. The definition has no temporal element, and nothing in the statute limits FDA's deeming authority to products or categories of products that are currently marketed. Contrary to Congress's intention in enacting the statute, the proposed interpretation would substantially impede FDA's ability to protect the public health. Indeed, FDA's ability to regulate new products would be further delayed by months or even years after the introduction of each new product, as the Agency would have to initiate a rulemaking to deem each new product before existing regulations would apply. Such an interpretation would frustrate the intent underlying the Tobacco Control Act and endanger the public health.

Moreover, we note that the Agency is not simply creating a rule to apply to theoretical products with completely unknown risks that will be developed in the future. Instead, FDA is finalizing this rule to include all "tobacco products" within the scope of its regulatory authority based on the potential harm posed by existing products and the Agency's experience with the regulation of such products (which have all been made or derived from tobacco). This experience has shown us that it would be easier for manufacturers and more protective for public health for a company to know (prior to development and marketing) that its product must be reviewed and authorized by FDA in order to be offered for sale in the United States.

(Comment 3) A number of comments contended that section 901(g) of the FD&C Act requires FDA to consult with other Federal Agencies before promulgating a new rule under chapter IX of the FD&C Act.

(Response) FDA agrees that section 901(g) requires FDA to "endeavor to consult with other Federal Agencies, as appropriate." FDA consulted with other Federal Agencies during the Federal Agency review process required by Executive Order 12866, satisfying its requirement under section 901(g).

2. FDA's Exercise of Authority

(Comment 4) Some comments, largely from the ENDS industry, argued that FDA is required to establish that deeming will benefit public health, and that insufficient evidence exists to do so. Specifically, they argued that FDA is unable to quantify the health risks of certain products (namely, e-cigarettes)[6] without multiple long-term studies, and that currently such studies do not exist. A few comments cited the public health standard in section 906(d) of the FD&C Act as authority for these claims.

(Response) FDA disagrees. These comments attempted to impose a standard for the application of FDA's deeming authority that is not created by statute or otherwise. Under section 901(b), chapter IX of the FD&C Act shall apply to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to *any other tobacco products that the Secretary by regulation deems to be subject to this chapter* (emphasis added). The only pertinent limitations on the scope of FDA's deeming authority are the definition of "tobacco product" set forth in section 201(rr) of the FD&C Act and a provision regarding tobacco growers and similar entities and tobacco leaf that is not in the possession of a manufacturer of tobacco products in section 901(c)(2) of the FD&C Act.

FDA disagrees with the comments that argued that the standard set forth in section 906(d) of the FD&C Act applies to the act of deeming tobacco products. Sections 901 and 906(d)(1) provide FDA with separate authorities. Section 901 gives FDA the authority to deem additional products to be subject to chapter IX. Once products are subject to chapter IX, FDA can use other authorities in chapter IX, such as section 906(d), to take regulatory action with respect to such products. By its own language, section 906(d) applies to regulations FDA issues requiring restrictions on the sale and distribution, including restrictions on the access to, and the advertising and promotion of, a tobacco product; therefore, the standard in section 906(d)(1) applies only to the additional regulations issued by FDA under section 906(d) (such as the minimum age and identification requirements and vending machine restrictions this rule is promulgating in § 1140.14, and the health warning requirements in §§ 1143.3 and 1143.5) and not to deeming itself or the provisions in the statute that apply automatically to newly deemed products.

Although FDA is not required to meet a particular public health standard to deem tobacco products, regulation of the newly deemed products will be beneficial to public health. The Agency has concluded, based on scientific data, that the newly deemed products should be regulated due to their potential for public harm (*e.g.*, 79 FR at 23154–23158) and regulation is necessary to learn more about that potential. Greater regulatory certainty created by premarket authorizations should help companies to invest in creating novel products, with greater confidence that improved products will enter the market without having to compete against equally novel, but more dangerous products. For example, a company wishing to invest the additional resources needed to ensure that its e-cigarette is designed and manufactured with appropriate methods and controls will be more likely to do so if the product is not competing against products that are more cheaply and crudely made, yet appear to be identical to the consumer. Over time, since the "appropriate for the protection of the public health" standard involves comparison to the general tobacco product market, FDA believes the employment of the premarket authorities could create incentives for producers to develop products that are less dangerous when consumed, less likely to lead to initiation of tobacco use, and/or easier to quit.

Further, FDA's premarket review of the newly deemed products will increase product consistency. For example, FDA's oversight of the constituents of e-cigarettes cartridges will help to ensure quality control relative to the chemicals and their quantities being aerosolized and inhaled. At present, there is significant variability in the concentration of chemicals amongst products—including variability between labeled content and concentration and actual content and concentration (*e.g.,* Refs. 16, 17, 18, 19, 20). Without a regulatory framework, users who expect consistency in these products may instead be subject to significant variability in nicotine content among products, raising potential public health and safety issues. Implementation of the premarket review requirements also will allow FDA to monitor product development and changes and to prevent more harmful or addictive products from reaching the market.

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[6] FDA notes that most comments referred to "e-cigarettes" when discussing ENDS products. Therefore, FDA refers to "e-cigarette" in the comment summaries. Because FDA's responses generally apply to all ENDS products (the most popular of which are electronic cigarettes, but also includes e-hookah, e-cigars, vape pens, personal vaporizers, and electronic pipes), FDA's responses to the comments generally use the term "ENDS."

In addition, as FDA discussed in the NPRM, deeming all tobacco products will provide FDA with critical information regarding the health risks of the products including information derived from ingredient listing submissions and reporting of HPHCs required under the FD&C Act (79 FR 23142 at 23148). Obtaining this information is particularly important given the addictiveness of nicotine and the toxicity associated with tobacco products. Given that "[e]xposure to secondhand tobacco smoke has been causally linked to cancer, respiratory, and cardiovascular diseases, and to adverse effects on the health of infants and children," this information will be helpful in further assessing the toxicity of the newly deemed tobacco products (Ref. 9 at 7).[7]

Many of these comments also argued that FDA's acknowledgment that it does "not currently have sufficient data . . . to determine what effects e-cigarettes have on the public health" is an admission that FDA does not know, and cannot determine, whether *regulation* of these products will benefit public health. FDA disagrees. That language follows the statement, "some have advanced views that certain new tobacco products that are noncombustible . . . may be less hazardous, at least in certain respects, than combustible products . . . ," and refers to the *lack* of evidence supporting such asserted benefits (79 FR 23142 at 23144). Whether ENDS generally may eventually be shown to have a net benefit on or harm to public health at the population level—and there have not yet been long-term studies conducted to support either claim at this time—*regulation* of ENDS will still benefit public health. The 2014 Surgeon General's Report also notes that "[f]urther research with attention to their individual and population-level consequences will be helpful to fully address these questions. However, the promotion of noncombustible products is much more likely to provide public health benefits only in an environment where the appeal, accessibility, promotion, and use of cigarettes and other combusted tobacco products are being rapidly reduced" (Ref. 9 at 874).

FDA noted in the NPRM that many public health benefits will flow from deeming tobacco products (including e-cigarettes and other ENDS). Even if a category of products were to prove generally beneficial, individual products within that category may raise concerns. For example, some products may be particularly attractive to youth or deliver unexpected high levels of toxicants. In addition, once all tobacco products are deemed, any manufacturer seeking to market its product as a modified risk tobacco product (MRTP) will be required to provide substantiation and obtain an order from FDA before making such claims, where it is currently not subject to such requirements under the FD&C Act. More generally, regulation and product review allows the Agency to help ensure the public health is protected. FDA's regulatory tools, including the adulteration and misbranding provisions in sections 902 (21 U.S.C. 387b) and 903 of the FD&C Act as applied to newly deemed products, will help to protect consumers by subjecting all tobacco products to certain basic requirements, such as that their labeling and advertising not be false or misleading. FDA will be able to take enforcement action against any tobacco products that do not meet these requirements. Further, implementation of the requirements regarding premarket applications, SE reports, and exemption requests (sections 905 and 910 of the FD&C Act (21 U.S.C. 387e and 387j, respectively)) will increase product consistency and help protect the public health from adverse impacts. For example, although there is currently variability in the concentrations of chemicals in e-liquids, FDA oversight of the constituents in e-liquids and ENDS will help to ensure quality control over the types and quantities of chemicals being aerosolized and inhaled (79 FR 23142 at 23149). Once deemed, the Tobacco Control Act authorizes FDA to impose certain types of restrictions that it has determined are appropriate to the protection of public health. Under this authority, FDA is imposing certain restrictions for ENDS and other products, such as minimum age requirements.

The need for deeming is further confirmed by the continued dramatic rise in youth and young adult use of tobacco products such as e-cigarettes and waterpipe tobacco, and continued youth and young adult use of cigars (mainly cigarillos). As discussed in the NPRM, e-cigarettes are widely available in retail outlets such as kiosks in shopping malls and on the Internet and their online popularity has surpassed that of snus which has been on the market far longer than e-cigarettes (Ref. 21).

Recent studies show a dramatic rise in the use of ENDS products. The Centers for Disease Control and Prevention (CDC) and FDA analyzed data from the 2011–2014 National Youth Tobacco Surveys (NYTS) and found that current (past 30 day) e-cigarette use among high school students increased nearly 800 percent from 1.5 percent in 2011 to 13.4 percent in 2014 (Ref. 22). In 2014, a total of 24.6 percent of high school students reported current use of a tobacco product (id.). Among all high school students, e-cigarettes (13.4 percent) were the most common tobacco products used (id.). This increase was not limited to any one demographic group; e-cigarettes were the most commonly used product among high school non-Hispanic whites, Hispanics, and persons of non-Hispanic other races (id.). E-cigarettes (3.9 percent) were also the tobacco product used most commonly by middle school students (id.). From 2011 to 2014, statistically significant nonlinear increases were observed among high school students for current e-cigarette use (1.5 percent to 13.4 percent) (id.). Among middle school students, statistically significant increases were observed from 2011 to 2014 (id.). In 2014, an estimated 4.6 million middle and high school students currently used any tobacco product (*i.e.,* cigarettes, cigars, smokeless tobacco, e-cigarettes, hookahs, tobacco pipes, snus, dissolvable tobacco, and bidis), of which an estimated 2.2 million students currently used two or more tobacco products. Overall, in 2014, 2.4 million middle and high school students reported current use of e-cigarettes (id.). The data also demonstrated that when use of all tobacco products was considered in aggregate, there was no change in overall current tobacco use among middle and high school students.

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[7] As stated in the 2014 Surgeon General's Report, "the burden of death and disease from tobacco use in the United States is overwhelmingly caused by cigarettes and other combusted tobacco products" (Ref. 9 at 7).

Another recently published study found that ninth grade students who reported having ever used e-cigarettes at the baseline assessment were approximately 2.7 times more likely than non-e-cigarette users to have started smoking combusted tobacco products (cigarettes, cigars, waterpipe tobacco) and 1.7 times more likely to have started smoking conventional cigarettes 6 to 12 months later (Ref. 23). While this study indicates that e-cigarette users are more likely than non-e-cigarette users to also use combusted tobacco products 12 months later, it cannot be determined by the research findings if such users would have used combusted tobacco products regardless of e-cigarette use. Researchers noted that some teens are more likely to use e-cigarettes prior to combustible tobacco products for several reasons including the availability of e-cigarettes in flavors attractive to youth (*id.*).

In terms of young adult and adult use of e-cigarettes, evidence from the most recent studies on ENDS use among young adults and adults indicates that among adults who had never smoked cigarettes, prevalence of ever e-cigarette use was highest among young adults aged 18 to 24 and decreased with increasing age (Ref. 24). However, current cigarette smokers and recent former smokers (*i.e.,* those who quit smoking within the past year) were more likely to use e-cigarettes than long-term former smokers (*i.e.,* those who quit smoking more than 1 year ago) and adults who had never smoked. Current cigarette smokers who had tried to quit in the past year were also more likely to use e-cigarettes than those who had not tried to quit (id.). It is noted that it cannot be determined by the research findings: (1) Whether former cigarette smokers who now exclusively use e-cigarettes would not have ceased smoking cigarettes regardless of e-cigarette use; and (2) whether the e-cigarette use preceded quitting or the quitting occurred first and then was followed by later e-cigarette use.

The data from the 2011 through 2014 NYTS also show that high school students' use of waterpipe tobacco more than doubled during this time period. In fact, researchers observed substantial increases in waterpipe tobacco use among both middle and high school students from 2011 through 2014 culminating in an estimated 1.6 million waterpipe tobacco youth users in 2014 (Ref. 22). From 2013 to 2014, prevalence almost doubled for high school students from 5.2 percent (770,000) to 9.4 percent (1.3 million) and more than doubled for middle school students from 1.1 percent (120,000) to 2.5 percent (280,000) (id.). These findings are consistent with earlier research on older youths and young adults discussed in the comments stating that waterpipe tobacco use continues to increase in popularity, particularly among college students, with as many as 40 percent reporting ever using waterpipe tobacco and 20 percent reporting current use (*i.e.,* use within the past 30 days) on some college campuses (Refs. 25, 26).

Likewise, youth continue to use cigars. Data from the 2014 NYTS indicate that 8.2 percent (1,200,000) of high school students and 1.9 percent (220,000) of middle school students had smoked cigars (including cigars, cigarillos, or little cigars) in the past 30 days (Ref. 22). Nineteen percent of students in 8th, 10th, and 12th grades participating in the Monitoring the Future study in 2014 also reported smoking small or little cigars (which represents a decrease from 23.1 percent in 2010, but it is unclear if subjects misidentified cigars as cigarettes during the study) (Ref. 27). In addition, the 2014 National Survey on Drug Use and Health (NSDUH) found that more than 2,500 youth under the age of 18 smoke their first cigar each day, nearly as many as those who smoke their first cigarette each day (more than 2,600) (Ref. 28). Nevertheless, data on youth cigar use from the Youth Risk Behavior Surveillance System (YRBSS) shows that current cigar use among youth (*i.e.,* use of a cigar, cigarillo, or little cigar on at least one day during the last 30 days) has declined between 1997 and 2013 (22 percent to 12.6 percent); however, no statistically significant change was observed between 2011 (13.1 percent) and 2013 (12.6 percent) (Ref. 29).

(Comment 5) At least one comment argued that the rule violates the APA, 5 U.S.C. 706, saying that it requires FDA to provide "the specific basis for [its] conclusion and the data on which each of [its] critical assumptions is based" (quoting *Ranchers Cattlemen Action Legal Fund United Stockgrowers of America,* No. 04–cv–51, 2004 WL 1047837 at *7 (D. Mont. Apr. 26, 2004), and FDA failed to do so.

(Response) FDA disagrees. The unpublished district court case quoted in the comment was reversed by the Ninth Circuit on exactly this point (415 F.3d 1078 (9th Cir. 2005)). The Ninth Circuit stated the correct standard: "All that is required is that the agency have 'considered the relevant facts and articulated a rational connection between the facts found and the choices made' " (id. at 1093). See *Citizens to Preserve Overton Park, Inc.* v. *Volpe,* 401 U.S. 402, 416 (1971); *Motor Vehicle Mfrs. Ass'n of U.S., Inc.* v. *State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 42–43 (1983).

In any event, the NPRM contains substantial explanation of FDA's reasoning in proposing this rule, including over 190 citations to scientific literature, and the NPRM and the final rule's supplementary information contain many pages explaining the data and comments considered, the conclusions drawn from the literature, and FDA's rationale for the final rule, fully satisfying the Administrative Procedure Act (APA).

(Comment 6) A few comments objected that FDA did not discuss the possibility of illicit markets in the proposed deeming rule, stating that FDA is required to consider the consequences of illicit markets under section 907(b)(2) of the FD&C Act.

(Response) FDA disagrees. Section 907(b)(2) does not apply to deeming, but rather applies only to the promulgation of regulations establishing tobacco product standards under section 907 of the FD&C Act. In any event, the Agency cannot refuse to act in furtherance of the public health because some individuals might violate the law. Nevertheless, FDA authority over the newly deemed tobacco products will give it means to determine which products are legally on the market and which are counterfeit or otherwise illegally marketed and to take enforcement action against manufacturers who sell and distribute illegal products. The Tobacco Control Act gives the Agency these and other authorities, such as section 920 of the FD&C Act (21 U.S.C. 387t), to help address illicit tobacco products.

3. Constitutional Issues

The Tobacco Control Act includes provisions restricting tobacco product marketing. As discussed in this document, some of these provisions apply to all products covered by the statute—including the newly deemed products—and others authorize FDA to impose additional restrictions. We received comments that argue that some of the restrictions this final rule imposes on newly deemed products violate the First Amendment.

a. Free Samples of Tobacco Products

(Comment 7) A few comments questioned the constitutionality of the ban on the distribution of free samples of tobacco products. (See § 1140.16(d)(1)).) First, the comments argued that distributing free samples is a form of commercial speech that is protected by the First Amendment and that the ban is unconstitutional as applied to the newly deemed products. Citing *Central Hudson Gas and Electric Corp.* v. *Public Services Commission,* 447 U.S. 557, 566 (1980), the comments argued that, accordingly, FDA must show that the ban is narrowly tailored to directly and materially advance a substantial State interest and that FDA failed to do so. The comments stated that while the court in *Discount Tobacco City & Lottery* v. *United States,* 674 F.3d 509 (6th Cir. 2012), *cert. denied sub nom. Am. Snuff Co., LLC* v. *United States,* 133 S. Ct. 1996 (2013) ("*Discount Tobacco*"), upheld the Tobacco Control Act's sampling ban on cigarettes, the evidence the court used to uphold that ban does not support the same ban for the newly deemed tobacco products. They argued that FDA has presented no evidence that samples of these products lead to youth initiation and, therefore, the Agency would not be advancing a legitimate government interest with this ban. Additionally, they suggested that even if the ban did advance a legitimate government interest, FDA could achieve the same results through less restrictive means, such as by allowing samples in qualified adult-only facilities, as FDA does with smokeless tobacco.

(Response) FDA disagrees that the ban on free samples is unconstitutional. First, although FDA acknowledges that in *Discount Tobacco,* 674 F.3d at 538–39, the Sixth Circuit treated the distribution of free samples as a form of commercial speech, FDA continues to believe that distribution of free samples is conduct not speech. Provisions that regulate conduct without a significant expressive element do not implicate the First Amendment. See *Arcara* v. *Cloud Books, Inc.,* 478 U.S. 697, 706–07 (1986). Additionally, a free sample ban is akin to a price restriction (*i.e.,* tobacco products cannot be free)—a "form[ ] of regulation that would not involve any restriction on speech." *44 Liquormart, Inc.* v. *Rhode Island,* 517 U.S. 484, 507 (1996) (opinion of Stevens, J.). Therefore, the free sample provision regulates the distribution of a product, and there is no First Amendment right to distribute free samples of a tobacco product.

Second, even if the distribution of free samples does implicate the First Amendment, as the Sixth Circuit concluded, the court went on to uphold the constitutionality of the restriction on free samples of tobacco products. *Discount Tobacco,* 674 F.3d at 541. In *Discount Tobacco,* as here, the manufacturers of tobacco products argued that the government failed to show that the ban would directly and materially advance the government interest of decreasing use of tobacco products by youth. The manufacturers further argued that even if the sampling ban were effective, there are less restrictive methods of preventing youth tobacco use (id. at 538, 541). The Sixth Circuit rejected both arguments, and held that the government "presented extensive documentation that free samples of tobacco products are [an] 'easily accessible source of these products to young people,' . . . and freely obtainable, even with the tobacco industry's 'voluntary codes that supposedly restrict distribution of free samples to underage persons'" id. at 541 (quoting 61 FR 44396 at 44460, 45244–45 & nn. 1206–08 (August 28, 1996)). The Court further held that free samples "may serve as the best advertisement of all for a product that is physiologically addictive, and socially attractive to youth" (id.).

The comments do not attempt to distinguish *Discount Tobacco.* Here, where there is a substantial government interest in preventing youth access to all tobacco products, and the newly deemed products, like the products considered by the Sixth Circuit Court of Appeals, are also "physiologically addictive, and socially attractive to youth," *Discount Tobacco* is directly on point. As we stated in the NPRM, the prohibition against free samples will eliminate a pathway for youth to access tobacco products, which can help in reducing youth initiation and therefore short-term and long-term morbidity and mortality resulting from these products.

Youth are uniquely susceptible to biological, social, and environmental influences to use and become addicted to tobacco products. See section X.A. As FDA recognized as early as 1995, "[f]ree samples give young people a 'risk-free and cost-free way to satisfy their curiosity' about tobacco products, and, when distributed at cultural or social events, may increase social pressure on young people to accept and to use the free samples" (60 FR 41314 at 41326 (quoting Ref. 30). For these reasons, we believe it is critical to prohibit the distribution of free samples of newly deemed tobacco products, which are highly addictive and can lead to a lifetime of tobacco use, with attendant adverse health consequences.

FDA received comments noting extensive sampling of some newly deemed products in venues that may attract youth, including:

- The major sellers of e-cigarettes distribute free samples in venues likely to attract large audiences.
- At least eight e-cigarette companies promote their products through sponsored or sampling events, many of which appear to be youth-oriented (Ref. 31).
- In 2012 and 2013 alone, 6 e-cigarette companies sponsored or provided free samples at 348 events, many of which were music festivals and motorsport events geared toward young people—including Grand Prix auto racing events (id.).
- Field research in Oregon found that e-cigarette retailers include the opportunity to sample the wide variety of flavored nicotine cartridges in their sales pitches with test stations for free sampling (Comments of Oregon Health Authority, FDA–2014–N–0189–76358).

As described above and in the NPRM, the free sample provision will address distribution of newly deemed tobacco products at venues such as these. Contrary to the assertions in the comments, FDA does not believe that it could achieve the same results by allowing samples of newly deemed products in qualified adult-only facilities, as FDA does with smokeless tobacco. In section 102(a)(2)(G) of the Tobacco Control Act (21 U.S.C. 387a–1(a)(2)(G)), Congress required FDA to reissue the final 1996 rule (published in the **Federal Register** of August 28, 1996, 61 FR 44396), with several changes, including the addition of a narrow exception to the free sample ban to allow for distribution of smokeless tobacco products in qualified, adult-only facilities (QAOFs). This exception is very prescriptive and operates only in very limited instances (*e.g.,* where the product is distributed in a specific type of temporary enclosed structure with age verification by a law enforcement officer or a security guard licensed by a governmental entity, and with the amount of smokeless tobacco per adult consumer subject to specific portion requirements). If FDA were to extend this exception, in whole or in part, to other tobacco products (when Congress explicitly extended the free sample ban to cigarettes and all "other tobacco products," which would include all future deemed tobacco products and laid out the qualified adult-only facility exception only for smokeless), FDA would have to justify such an exception in light of the potential adverse public health impact of allowing free samples and determine the particular parameters of the exception as appropriate for newly deemed tobacco products. This would include, at a minimum, parameters relating to type of facility, means of access, type(s) of tobacco products distributed, and portion sizes for each type of tobacco product for which FDA is creating an exception. Newly deemed products have been largely unregulated and their markets, particularly for novel noncombustible products such as ENDS, are dynamic. Comments did not provide evidence demonstrating that the distribution of free samples of newly deemed tobacco products would be consistent with protecting public health. While there is evidence suggesting that distribution of tobacco products is harmful (*e.g.*, courts have expressed concern that free samples can provide young people with easy access to tobacco products), FDA has not yet obtained product-specific evidence and, therefore, cannot set limits for the quantities or portion sizes of products taken away from a QAOF that are commensurate with the current exception for smokeless tobacco products. Therefore, QAOFs could still allow for access to tobacco products in a manner that will have a negative public health impact.

Prohibiting free samples is a minor restriction on distribution, and tobacco product manufacturers, distributors, and retailers remain free to inform consumers about their products. The free sample prohibition does not interfere with the ability of a manufacturer, distributor or retailer to communicate truthful and nonmisleading information to adult consumers. We further address this prohibition and respond to additional comments in section XI.F.

(Comment 8) Some comments recommended that FDA exempt e-cigarettes from the prohibition on free samples. In the alternative, the comments recommended that FDA restrict the circumstances in which free samples may be given to adult consumers. For example, comments suggested that FDA require age verification for each recipient of a free sample and limit the amount of free products that recipients may take away from an event in which samples are distributed.

(Response) We disagree for the reasons discussed in the response to the previous comment. As stated in the NPRM, prohibiting free samples eliminates a pathway to tobacco products for youth, which can help to reduce initiation and thus decrease morbidity caused by use of tobacco products (79 FR 23142 at 23149). In addition, the United States Court of Appeals for the Sixth Circuit previously recognized that FDA has provided "extensive" evidence that free tobacco samples constitute an "easily accessible source" for youth (*Discount Tobacco City & Lottery, Inc.* v. *United States*, 674 F.3d 509, 541 (6th Cir. 2012) (citing 61 FR 44396 at 44460, August 28, 1996), *cert. denied sub nom. Am. Snuff Co., LLC* v. *United States*, 133 S. Ct. 1966 (2013)). With the growth in the use of ENDS, particularly by youth (see section VIII.B), a free sample prohibition is necessary to reduce youth access to ENDS and possibly a transition to combusted tobacco products (see Ref. 23).

b. Modified Risk Tobacco Products

Section 911 of the FD&C Act (21 U.S.C. 387k) prohibits the introduction or delivery for introduction into interstate commerce of any MRTP without an FDA order in effect under section 911(g). An MRTP is a tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products; this includes tobacco products, the product label, labeling, or advertising of which represents that it is less harmful or presents a lower risk of disease than other tobacco products.

(Comment 9) A comment from one tobacco company argued that section 911 is unconstitutional on its face. This comment argued, at length, that FDA's oversight of claims that a particular tobacco product is safer than others violates the First Amendment—even as applied to currently regulated products, such as cigarettes.

(Response) Comments addressed to the facial constitutionality of a statute are generally outside the scope of an agency's rulemaking authority. *Am. Meat Inst.* v. *U.S. Dep't of Agric.*, 760 F.3d 18, 25 (D.C. Cir. 2014) (*en banc*) ("We do not think the constitutionality of a statute should bobble up and down at an administration's discretion."). That said, FDA disagrees with the challenges against section 911's constitutionality. The Sixth Circuit considered and unanimously rejected the same argument in *Discount Tobacco*, 674 F.3d at 531–37, and the Supreme Court denied the manufacturers' petition for a writ of certiorari (133 S. Ct. 1966 (2013)). As the Sixth Circuit explained, section 911 requires that a manufacturer establish health claims for particular tobacco products to FDA before marketing, rather than allow only post-market review of such claims (674 F.3d at 537 ("it would be a virtual impossibility to unring the bell of misinformation after it has been rung")). This provision does not "infringe significantly on noncommercial speech" since it leaves "untouched" manufacturers' "ability to make 'direct comments on public issues'" (id. at 533 (citation omitted)). Instead, the court held, what section 911 restricts is commercial speech, since it applies to consumer-directed claims regarding a manufacturer's specific products (id.). That restriction on commercial speech, the court held, is constitutional under *Central Hudson Gas & Electric Corp.* v. *Public Service Commission*, 447 U.S. 557 (1980): It advances a substantial government interest in preventing inaccurate and harmful health claims about tobacco products of the sort that the industry has made for many decades, and it is sufficiently tailored because it concerns only consumer-targeted speech about tobacco products' health effects or contents and is no more extensive than warranted. *Discount Tobacco*, 674 F.3d at 534–37. FDA observes that this comment did not address *Discount Tobacco's* holding or the Sixth Circuit's analysis.

(Comment 10) A few comments argued that section 911 may violate the First Amendment if it is applied to ban descriptions of e-cigarettes and other noncombustible products as "smokeless" or "smoke-free."

(Response) FDA has carefully considered the comments that argued that noncombusted products, including ENDS, should be permitted to use the terms "smokeless" and smoke-free" to describe their products. We note that section 911 provides that "No smokeless tobacco product shall be considered to be [an MRTP] solely because its label, labeling, or advertising uses the following phrases to describe such product and its use: 'smokeless tobacco,' 'smokeless tobacco product,' 'not consumed by smoking,' 'does not produce smoke,' 'smokefree' [and four more similar terms]." However, this provision only applies to "smokeless tobacco," which is explicitly defined in the FD&C Act as "any tobacco product that consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral or nasal cavity" (section 900(18) of the FD&C Act). ENDS do not fall within that definition. Moreover, in contrast to ENDS, consumption of "smokeless tobacco products," as defined, does not require the use of heat, inhalation of the product into the lungs, or exhalation of constituents into the close environment. FDA is also aware that some e-cigarettes are heated to a high enough level to cause combustion of the e-liquid. For these reasons, and until FDA obtains product-specific evidence, the Agency will evaluate an ENDS manufacturer's use of "smokeless" or "smoke-free" (and similar descriptive terms) on a case-by-case basis, and the Agency will continue to apply the MRTP provisions in a manner consistent with the statute and Constitution. This case-by-case approach to "smokeless," "smoke-free," and similar terms is appropriate as applied to ENDS, which encompasses a broad, heterogeneous, and evolving category of products.

4. Required Warning Labels

This final rule requires advertising and packaging warnings for newly deemed covered tobacco products and for cigarette tobacco and roll-your-own tobacco, as authorized by Section 906(d) of the FD&C Act, 21 U.S.C. 387f (d). Packaging and advertising for all newly deemed products other than cigars must display an addictiveness warning that states: "WARNING: This product contains nicotine. Nicotine is an addictive chemical." (Subject to certain requirements, the manufacturer of a product that does not contain nicotine may use an alternative warning that states: "This product is made from tobacco.") Packaging and advertising for cigars must display either the addictiveness warning, or one of five others specified in the rule.

The final rule requires the warnings to appear on at least 30 percent of the two principal display panels of the package, and at least 20 percent of the area of advertisements. These are the same warning sizes Congress established for smokeless tobacco in the Tobacco Control Act: At least 30 percent of smokeless-tobacco packaging's two principal panels, and at least 20 percent of the area of each advertisement. 15 U.S.C. 4402(a)(2)(A), (b)(2)(B). In the same Act, Congress prescribed an even larger size for cigarette warnings: 50 percent of the front and rear panels of cigarette packaging (and the same 20 percent size for cigarette advertisements) (15 U.S.C. 1333(a)(2), (b)(2)). (The larger warning sizes required for cigarettes have not yet been implemented, because FDA's initial regulations implementing a graphics component for cigarette warnings were vacated by the DC Circuit Court of Appeals in *R.J. Reynolds Tobacco Co.* v. *FDA*, 696 F.3d 1205 (D.C. Cir. 2012), *overruled on other grounds by Am. Meat Inst.*, 760 F.3d at 22–23.)

A detailed discussion of the warning requirements appears in section XVI.

a. First Amendment Challenges

The required warnings are a form of compelled disclosure, and are thus subject to First Amendment scrutiny. *Milavetz, Gallop & Milavetz, P.A.* v. *United States*, 559 U.S. 229, 249 (2010); *Riley* v. *Nat'l Fed'n of the Blind of N.C., Inc.*, 487 U.S. 781, 797–98 (1988).

(Comment 11) Although the comments generally did not dispute the need for warning labels, some commenters questioned the accuracy of the addictiveness warning as applied to cigars, contending that cigar users do not always inhale.

(Response) Nicotine is "one of the most addictive substances used by humans" (Ref. 7). "Because the extension of First Amendment protection to commercial speech is justified principally by the value to consumers of the information such speech provides," the manufacturers' "constitutionally protected interest in *not* providing any particular factual information in his advertising is minimal." *Am. Meat Inst.*, 760 F.3d at 26 (quoting *Zauderer* v. *Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985)).

Cigar packaging and advertisements are required to display one of six warnings, one of which is the addictiveness warning. Research indicates that most cigar smokers do inhale some amount of smoke, even when they do not intend to inhale, and are not aware of doing so (Refs. 32, 33). Even when cigar smokers do not breathe smoke into their lungs, they are still subject to the addictive effects of nicotine through nicotine absorption (Refs. 32, 34). This is because cigar smoke dissolves in saliva, allowing the smoker to absorb sufficient nicotine to create dependence, even if the smoke is not inhaled (Refs. 34, 35).

(Comment 12) A few comments argued that the First Amendment prohibits a requirement for covered tobacco products to carry warning labels that cover 30 percent of the two principal display panels of the packaging. These comments argued that manufacturers have limited space on packaging to communicate information to consumers, including branding and marketing information, and that requiring manufacturers to dedicate 30 percent of that space for a warning is unduly burdensome, because it prevents manufacturers from using that space to convey their own messages. The comments argued that the warning label presents a simple message that could be relayed in a smaller space.

(Response) FDA disagrees. In *Discount Tobacco*, the Sixth Circuit considered and rejected the same First Amendment arguments against the size required by the Tobacco Control Act for cigarette and smokeless tobacco warnings. *Discount Tobacco*, 674 F.3d at 567. The court found ample evidence supporting the size requirements, and held that the manufacturers failed to show "that the remaining portions of their packaging [were] insufficient for them to market their products" (id. at 564–66, 567). The comments argued that the requirement that the warning cover 30 percent of the two principal display panels is unduly burdensome and would prevent manufacturers of newly deemed products from communicating information about their products. As in *Discount Tobacco*, the comments failed to substantiate that claim with evidence. Nor did the comments provide evidence that the same size requirements for smokeless tobacco—which have been in force since 2010—have unduly burdened the speech of smokeless tobacco manufacturers.

As the court explained in *Discount Tobacco*, Congress required larger warnings for smokeless tobacco and cigarettes in the wake of the Surgeon General's conclusion that existing warnings were "'given little attention or consideration by viewers'" and IOM's analysis showing that those warnings "'fail[ed] to convey relevant information in an effective way.'" *Discount Tobacco*, 674 F.3d at 562 (quoting Refs. 3, 7).

The comments contending that the warning label size is burdensome or unjustified are misplaced for the same reasons identified by the *Discount Tobacco* court. After emphasizing that the relevant First Amendment standard looks only to whether mandatory warnings are reasonably related to the government's interest, *Discount Tobacco*, 674 F.3d at 567 (citing *Zauderer* v. *Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985)), the Sixth Circuit held that the required cigarette warning labels, which were to cover 50 percent of the two primary panels of cigarette packs (far more than the 30 percent required here), did not violate the First Amendment because "[a]mple evidence supports the size requirement for the new warnings . . . and Plaintiffs have not shown that the remaining portions of their packaging are insufficient for them to market their products." (674 F.3d at 567; see also id. at 530–31 (Clay, J., concurring in result) (finding that the government demonstrated that the Tobacco Control Act's size and placement requirements satisfied *Zauderer* scrutiny).)

Article 11 of the Framework Convention on Tobacco Control (FCTC), evidence of a strong worldwide consensus regarding a regulatory strategy for addressing the serious negative impacts of tobacco products,[8] recognized the importance of having warnings cover at least 30 percent of the area of the two principal display panels. The European Union (EU) requires that health warnings comprise 30 percent of the area on the front of the package and 40 percent on the back of the package

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[8] There are 180 parties to the WHO's FCTC as of November 2015. At this time, the United States is a signatory but has not ratified this treaty.

(2001/37/EC). Users are more likely to recall warnings that are in a larger size and that appear on the front/major surfaces of the tobacco product package. (Ref. 7). Before a warning label can help a consumer better understand and appreciate the risks against which it warns, the consumer must notice and pay attention to the warning. The likelihood that a consumer will do so depends upon warning's size and position. (Refs. 36, 37, 38, 39, 40).

Some comments sought to support their First Amendment arguments against the warning label sizes by citing the D.C. Circuit's decision in *R.J. Reynolds* v. *FDA,* 696 F.3d 1205 (D.C. Cir. 2012), which vacated specific cigarette warnings previously issued by FDA. However, the decision in *Reynolds* was based on the graphics components of the cigarette warnings, not their size. Moreover, the reasoning of the *Reynolds* panel decision was overtaken by the D.C. Circuit's more recent *en banc* decision in *American Meat Institute,* 760 F.3d at 22–23.

FDA recognizes that the warning size requirement for covered tobacco products may present special difficulties for products in particularly small packages. To address this concern, FDA has added subsection (d) to § 1143.4. Under § 1143.4(d), a product that is too small or otherwise unable to accommodate a label with sufficient space to bear the required warning, printed in the required font size, may instead carry the warning on the carton or other outer container or wrapper. In cases where there is no carton or other outer container or wrapper that is large enough to carry the warning, the product may carry the warning on a tag firmly and permanently affixed to the package.

FDA agrees that other warnings on tobacco product packages, such as a warning regarding the risk of nicotine poisoning (as suggested by one particular comment), may also provide consumers with important health risk information. Therefore, elsewhere in this issue of the **Federal Register**, FDA has made available draft guidance, which when final will describe FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products, including recommendations for exposure warnings that would help to support a showing that a product is appropriate for the protection of public health. FDA also has issued an ANPRM seeking comments, data, research, or other information that may inform regulatory actions FDA might take with respect to nicotine exposure warnings and child-resistant packaging for certain tobacco products. If FDA determines that it is appropriate for the protection of the public health to require such a warning (in addition to the addiction warning), FDA will consider at that time whether it is necessary to change the formatting requirements for the addiction warning to ensure that all warnings are clear and conspicuous.

b. Preemption of State Law Warning Requirements

(Comment 13) A number of comments sought an affirmative statement from FDA that the NPRM preempts State and local warning requirements. A few of the comments directly referenced California's reproductive health warning requirements for products containing nicotine (a notice mandated by Proposition 65). Many cited the explicit preemption provisions that apply to cigarettes and smokeless tobacco (see 15 U.S.C. 1334(b) and 4406(b)). One manufacturer argued that it would be arbitrary and capricious to subject the newly deemed products to a patchwork of Federal, State, and municipal requirements, while cigarettes and smokeless tobacco warning requirements are uniform across States and potentially less stringent. The comment further argued that it would be particularly unreasonable to subject noncombusted products to State and local labeling requirements because (according to the comment) noncombusted products are "safer than cigarettes."

Taking the other side of the issue were comments from public health groups and a joint comment from 29 State Attorneys General who advocated for an explicit statement that the NPRM does *not* preempt State and local warning requirements, including California's Proposition 65. At a minimum, they suggested that FDA change the heading of part 1143 from "Required Warning Statement" to "Minimum Required Warning Statement" to indicate that the deeming rule does not preclude other health warnings.

(Response) Section 916(a)(1) of the FD&C Act (21 U.S.C. 387p) expressly preserves the authority of State and local governments to, among other things, enact and enforce laws regarding tobacco products that are in addition to, or more stringent than, requirements established under chapter IX of the FD&C Act. The preservation of State and local governmental authority over tobacco products is limited by section 916(a)(2) of the FD&C Act, which expressly preempts any State or local requirement that is different from, or in addition to, any requirement under chapter IX of the FD&C Act relating to tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing practices, or MRTPs.[9] However, section 916(a)(2)(B) of the FD&C Act states that the express preemption provision in section 916(a)(2)(A) does not apply to requirements relating to, among other things, the sale, distribution, possession, information reporting to the State, exposure to, access to, the advertising and promotion of, or use of, tobacco products by individuals of any age. A State or local statute is facially preempted only if no set of circumstances exists under which the statute would be valid. (See *Comm. of Dental Amalgam Mfrs. & Distribs.* v. *Stratton,* 92 F.3d 807, 810 (9th Cir. 1996).) FDA notified State and local jurisdictions about the potential impact this rule could have on their requirements. No State or local laws in effect at the close of the public comment period were identified that FDA determined would be preempted by this final rule.

With respect to the argument that it would be arbitrary and capricious to allow States and localities to subject newly deemed products to different warning requirements than cigarettes and smokeless tobacco products, we note that the preemptive effect depends on the relevant statutes. The preemption provisions of the Federal Cigarette Labeling and Advertising Act of 1965 (FCLAA) (15 U.S.C. 1334) and the Comprehensive Smokeless Tobacco Health Education Act of 1986 (CSTHEA) (15 U.S.C. 4406), which apply to cigarettes and smokeless products, respectively, are significantly different from section 916 of the FD&C Act. For example, the FCLAA and CSTHEA provisions expressly preempt State and local regulation of the content of cigarette and smokeless product advertisements, while section 916(a)(2)(B) of the FD&C Act exempts State and local advertising restrictions from preemption.

Separate and apart from the issue of preemption, elsewhere in this issue of the **Federal Register**, FDA has made available draft guidance, which when final will describe FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products, including recommendations for exposure warnings that would help support a showing that a product is appropriate for the protection of public health. Additionally, FDA notes that some ENDS product manufacturers have voluntarily included exposure warnings on their products. Accordingly, FDA has changed the heading of part 1143 from "Required Warning Statements" to "Minimum Required Warning Statements" in order to clarify that part 1143 is not intended to prevent tobacco product manufacturers from including truthful, non-misleading warnings on their products' packaging or advertisements voluntarily or as a result of FDA guidance.

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[9] We note that while section 906(e) of the FD&C Act refers to "good manufacturing practices," FDA refers to any regulations that could be issued under section 906(e) as tobacco product manufacturing practices.

III. Use of Premarket Pathways for Newly Deemed Products

As stated in the proposed deeming rule, manufacturers of newly deemed products that are "new tobacco products" as defined in section 910(a)(1) of the FD&C Act will be required to obtain premarket authorization of their products through one of three pathways—SE., exemption from SE., or premarket tobacco product application (PMTAs) (sections 905 and 910 of the FD&C Act). The substantive requirements of these provisions are set by statute and, thus, have not changed from the NPRM. However, FDA has revised the compliance periods for submitting premarket applications, as discussed in section V.A.

As an initial matter, with this final rule, we are also clarifying when FDA will consider a document to have been submitted for purposes of the compliance periods for submission of documents and data required by the automatic provisions of the statute. In the NPRM, we noted that the automatic provisions require companies to submit information to FDA, and we proposed various compliance periods to provide industry with time to make such submissions (*e.g.*, "the manufacturer submits a 905(j) report for the product by [effective date of part 1100 plus 24 months]"). As previously discussed publically (see *http://www.fda.gov/tobaccoproducts/newsevents/ucm393894.htm*), FDA generally relies on the date of receipt of a submission by FDA's Document Control Center (DCC) as the date that the document was submitted (not the date that the submitter sent it). The DCC has been and will continue to be fully equipped to receive tobacco product submissions (including the number of submissions expected at the close of compliance periods). Therefore, regulated entities should ensure that FDA's DCC receives any submission by the due date or end of compliance period. The time it takes to review a premarket application is dependent upon the type of application and the complexity of the product. FDA has taken many steps to reduce the previous backlog and prevent further backlogs of marketing applications pending FDA review. FDA intends to act as expeditiously as possible with respect to all new applications, while ensuring that statutory standards are met. If an applicant wishes to discuss a product application, the applicant may request a meeting as set forth in FDA's final guidance entitled "Meetings with Industry and Investigators on the Research and Development of Tobacco Products" (announced May 25, 2012, 77 FR 31368).

In addition, we are clarifying that FDA distinguishes between a marketing application that has been "filed," one that "has been accepted," and one that has been "submitted" to FDA. A marketing application has been "submitted" when a complete application is delivered and received electronically, through the mail, or through a courier to CTP's Document Control Center (DCC). Once a complete PMTA application is submitted and received by CTP's DCC, FDA will have 180 days to consider the application as described in section 910(c)(A) of the Tobacco Control Act. A marketing application "has been accepted" after the Agency completes a preliminary review and determined that the application on its face contains information required by the statutory and/or regulatory provisions applicable to that type of application. A marketing application has been "filed" after the Agency completes a threshold review and has determined that a complete, substantive review is warranted. This filing review occurs only for a PMTA or a modified risk application and results in either a filing letter or a refusal to file letter.

A. Background: The Three Pathways To Market a New Tobacco Product

We received a large number of comments addressing the pathways to market a new tobacco product. Comments from industry argued that the review process for a new tobacco product is simply too difficult—that the standard is too high, and that the burden of submitting an application is too great. Many manufacturers of the newly deemed products argued that the two alternative pathways—SE and the SE exemption—are not available to them because there is no predicate to which they can claim SE. We address these comments in the following sections.

Under section 910 of the FD&C Act, manufacturers must receive FDA's permission to market new, including newly modified, tobacco products in the United States. The provision applies to all tobacco products covered by the FD&C Act, however, those that were commercially marketed in the United States on February 15, 2007 (the grandfather date) do not constitute new tobacco products and therefore do not require such premarket authorization. See section 910(a) of the FD&C Act (defining "new tobacco product" as any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007, or has been modified since that date).

Products that were introduced or modified after the grandfather date may seek permission to market under one of three pathways. The manufacturer may submit a PMTA, which is an application that requires the manufacturer to provide information about the product, including ingredients, additives, properties, manufacture, processing, labeling, and health risks, among other things (section 910(b) of the FD&C Act). FDA will grant permission to market the new product if the PMTA shows that it would be appropriate for the protection of the public health, among other things (section 910(c)(2) of the FD&C Act; see also section 910(c)(4) (requiring FDA to consider the risks and benefits to both users and nonusers, and explicitly requiring FDA to consider the effect of marketing the product on the likelihood that existing users of tobacco products will stop using them, and the likelihood that nonusers of tobacco products will start)). Whether the marketing of a product is appropriate for the protection of the public health will be evaluated on a case-by-case basis (in accordance with Section 910(c)(4) of the FD&C Act) and with consideration of the continuum of risk of nicotine-delivering products. The statute instructs FDA to base its findings regarding whether marketing the tobacco product would be appropriate for the protection of public health on well-controlled investigations, which may include one or more clinical investigations, where appropriate. However, it also allows FDA to authorize that its findings be made on the basis of valid scientific evidence other than controlled studies if FDA finds such other evidence sufficient to evaluate the tobacco product (section 910(c)(5) of the FD&C Act). We received several comments addressing the burden the PMTA application places on manufacturers, including the expense and time that clinical studies require.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a draft guidance, which when final will provide the Agency's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products, including specific recommendations concerning how to support a showing that the marketing of a new tobacco product is appropriate for the protection of the public health.

The second pathway to market is the SE pathway, which allows for a manufacturer to apply for permission to market a tobacco product that it demonstrates is "substantially equivalent" to a tobacco product that was marketed on the grandfather date or to a product previously found substantially equivalent (the "predicate") (section 910(a)(2)(A) and section 905(j) of the FD&C Act). To receive marketing authorization under the SE pathway, a manufacturer must submit an application that shows that the product to be marketed has the same characteristics as the predicate tobacco product or has different characteristics and the information submitted contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that it is not appropriate to regulate the product under section 910 because the product does not raise different questions of public health (section 910(a)(3)(A) of the FD&C Act). The statute defines "characteristics," for this purpose, as the materials, ingredients, design, composition, heating source, or other features of a tobacco product (section 910(a)(3)(B) of the FD&C Act).

As new tobacco products continue to evolve from the cigarettes and smokeless tobacco that were on the market on the grandfather date, the SE pathway may not be available for some new products. The availability of the SE pathway for the newly deemed products was the subject of many comments, with some arguing that a different, later grandfather date should be adopted, and others arguing there should be no change in the grandfather date and that the newly deemed products should proceed through the PMTA pathway if no appropriate predicate is available.

Under the third pathway, a product may be exempted from the SE requirements if the only change to the product is a minor change and that change only involves a change to an additive in a tobacco product that can be sold under the FD&C Act, for which an SE report is not necessary and where the exemption is otherwise appropriate, as discussed in section 905(j)(3) of the FD&C Act.

B. Interpretation of Substantial Equivalence

(Comment 14) Some comments argued that FDA should interpret "substantial equivalence" broadly so that newly deemed products could avoid what the comments characterize as the more burdensome new tobacco product application (PMTA) pathway with a showing that the product has some similar characteristics to the predicate products.

(Response) FDA disagrees. SE is explicitly defined in section 910(a)(3) of the FD&C Act, which provides, in relevant part, that the term "substantially equivalent" or "substantial equivalence" means that the Secretary by order has found that the tobacco product: (1) Has the same characteristics as the predicate tobacco product or (2) has different characteristics and the information submitted contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that it is not appropriate to require a PMTA because the product does not raise different questions of public health. Section 910(a)(3)(B) provides that the term "characteristics" means the materials, ingredients, design, composition, heating source, or other features of a tobacco product. A product must have the same characteristics—all of the same characteristics—as the predicate product, to be found substantially equivalent under section 910(a)(3)(A)(i) of the FD&C Act or if the new product has different characteristics FDA must find that the new product does not raise different questions of public health under section 910(a)(3)(A)(ii).

FDA notes that for newly deemed products about which concerns have been raised with respect to the availability of an appropriate predicate—*e.g.*, e-cigarettes—many of these products have entirely different characteristics from traditional tobacco products. As such, a manufacturer would need to satisfy section 910(a)(3)(A)(ii) (*i.e.*, demonstrate that the new product does not raise different questions of public health as compared to the predicate). FDA is continuing to research e-cigarettes, other ENDS, and heated cigarette products that likely were on the market on February 15, 2007, and is working to determine the availability of such products for comparison. FDA determined that some e-cigarettes were manufactured in 2006 and introduced into the United States in early 2007. In particular, we have identified a non-flavored e-cigarette (also marketed as an "e-cigar") that may have been on the market on February 15, 2007. This product may possibly be able to serve as an appropriate predicate for purposes of the SE pathway. The burden of demonstrating that a valid predicate exists rests with the manufacturer submitting a SE report. To facilitate the determination that a product is eligible as a predicate for an SE application, any individual who has evidence that an e-cigarette or other tobacco product was commercially marketed in the United States on February 15, 2007, is encouraged to contact the Agency at 1–877–CTP–1373. Regardless of the predicate selected for comparison, manufacturers are responsible for providing scientific data adequate to demonstrate that, in the case of an SE Report, the characteristics are the same or, if the characteristics are different, these differences do not cause the new product to raise different questions of public health. It should also be noted that, where the predicate and new products are in a different category or subcategory, the evidence needed to obtain marketing authorization through the PMTA pathway may be similar to gather and submit than that needed for the SE pathway. For example, as stated in the NPRM, it is possible that an applicant may not need to conduct any new nonclinical or clinical studies for PMTA, while in other cases, such as where there is limited understanding of a product's potential impact, nonclinical and clinical studies may be required for market authorization. In cases where no new nonclinical or clinical studies are needed, the effort associated with gathering and submitting a PMTA may not be materially greater than that for an SE Report.

As stated earlier, the FD&C Act does not place limitations on which pathway manufacturers can use to seek market authorization for a new product. Thus, manufacturers may choose to submit applications under any of the three legal pathways. To obtain marketing authorization under the PMTA pathway, manufacturers are required to establish, among other things, that permitting their products to be marketed would be appropriate for the protection of public health. In establishing this, manufacturers should take into account, and FDA will consider, the ways in which the new product is likely to be used. For example, PMTAs for these products should contain information on whether the product is likely to be used alone or together with other legally marketed tobacco products (such as available delivery systems), as well as the type and range of other products with which it is likely to be used.

For example, where a manufacturer seeks authorization of a new e-liquid to be used with ENDS, the manufacturer may need to provide evidence and analysis of the product's likely impact when used in the range of delivery systems available. Similarly, a manufacturer seeking authorization of a stand-alone apparatus component—such as a heating coil or cartridge—may need to provide evidence and analysis of the product's likely impact when used together with the range of other components and liquids available.

In the case of e-liquids, FDA expects that it may be possible for manufacturers to satisfy the statute by demonstrating that marketing of the liquid is appropriate for the protection of public health as it may be used in any of the legally available delivery systems. While FDA recognizes that there may remain some degree of uncertainty in any such analysis, FDA expects that the range of delivery system specifications authorized by FDA will provide a sufficiently specific spectrum of possibilities, such that a meaningful public health impact analysis can be done.

In the case of ENDS hardware/apparatus components, FDA expects that it may be difficult for manufacturers to make the showing necessary to meet the statutory standard, given the great extent of possible variations in combinations of hardware components, if all are considered and sold separately. Thus, with respect to apparatus, FDA expects that manufacturers will be most successful where authorization is sought for entire delivery systems, rather than individual components. In the case of these complete delivery systems—systems for which the application covers all potential parts, including customizable options as applicable, and where labeling, instructions for use and/or other measures are used to help ensure use as intended—FDA expects that the range of possible outcomes may be narrow enough for the manufacturer to demonstrate, and for FDA to assess, public health impact.

(Comment 15) Some comments asserted that under section 910(a)(3)(A)(ii) of the FD&C Act, certain categories of products should easily meet the SE standard because the products, overall, are beneficial to public health when compared to traditional, combustible cigarettes.

(Response) The issue of whether a product or certain categories of products may be beneficial to an individual is different than whether a category of products, overall, has a net positive benefit on population health. As explained in the NPRM, a category of products may benefit some individual tobacco users but may not have an overall net population health benefit if it leads to increased tobacco product initiation or dual use. In any event, this is a consideration relevant under the PMTA standard, not the SE standard.

Under section 910(a)(3)(A)(ii), a product can be found substantially equivalent to a predicate product even if it does not share all of the same characteristics of the predicate, if the information submitted contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that it is not appropriate to require a new product application because the product does not raise different questions of public health as compared to the predicate.

FDA will authorize the marketing of products through the SE pathway that meet the applicable standards in the FD&C Act. However, the SE pathway is a comparison between a new tobacco product and a predicate identified by the submitter, not an evaluation of whether the product is appropriate for the protection of the public health more generally as would be conducted under an application under section 910(b) (*i.e.*, a PMTA). Therefore, some differences between new and predicate products may not be appropriate for an SE Report, and the product instead is more suited to seeking authorization using a PMTA. Additionally, as the SE pathway is a specific comparison between a predicate and a new tobacco product, it does not necessarily provide a pathway to market for entire categories of products. Rather, under section 910(a)(3)(A)(ii), an application for SE must show that any differences in characteristics between the product and the predicate "do not raise different questions of public health."

(Comment 16) A small number of comments argued that newly deemed products should be permitted to be marketed under the SE pathway even if they do not share the same characteristics as the claimed predicate.

(Response) The statute does allow for applicants to use the SE pathway for new tobacco products that have different characteristics than the predicate product. To receive a marketing authorization under the SE pathway, these applicants must show that the new product has different characteristics and the information submitted contains information, including clinical data if necessary, to show that the product does not raise different questions of public health (section 910(a)(3)(A)(ii)).

(Comment 17) A few comments argued that section 910(a)(3)(A)(ii) allows for cross-category comparisons (*i.e.*, applicants may provide a comparison to predicate products from similar (but not identical) tobacco product categories).

(Response) It is up to the manufacturer to select an appropriate predicate tobacco product and provide the scientific evidence demonstrating SE. If the manufacturer provides scientific evidence and a rationale that demonstrates to FDA that the new product does not raise different questions of public health than the predicate (even though there are differences from the predicate product), FDA could issue an SE order. However, manufacturers of cigars or ENDS would have great difficulty showing that a product is substantially equivalent to a combusted cigarette or a smokeless tobacco product. For example, if FDA received an SE Report for a new product that is an ENDS closed aerosol generating apparatus and a predicate product that is a filtered combusted cigarette, then the product characteristics between the new and predicate products would be different. Because of the differences in characteristics in this example, a significant amount of scientific evidence would be needed to demonstrate that the new product does not raise different questions of public health. Such evidence, as discussed in FDA's 2011 Guidance titled "Section 905(j) Reports: Demonstrating Substantial Equivalence," could include but would not be limited to the following: (1) Smoke yield data from HPHCs, (2) actual use data demonstrating how smoke topography compares between the new and predicate products, (3) actual use data demonstrating how the amount of product use varies between the new and predicate products (*e.g.*, number of puffs per day), and (4) marketing data indicating how consumer perception (product appeal) by youth differs between the new and predicate products. In these cases, it would be difficult to show that the differences between the product and the predicate product are such that the product "does not raise a different question of public health."

In addition, the evidence required to make such a showing may be as substantial or even greater than the evidence required under the PMTA pathway (section 910(b)), and the PMTA pathway allows for different effects on public health—as long as the applicant provides a demonstration that the product is appropriate for the protection of the public health. Nevertheless, there is nothing in the statute to prohibit the attempted use of cross-category comparisons in an SE submission, but it is the responsibility of the manufacturer to provide appropriate and sufficient evidence to support a finding of SE.

(Comment 18) A few comments from industry argued that FDA should interpret "substantial equivalence" as the term is applied to medical devices under section 510(k) of the FD&C Act (21 U.S.C. 360(k)), which does not require premarket review for what the comments refer to as "even the slightest change to a predicate."

(Response) FDA's interpretation of SE with respect to medical devices is based on a different statutory section than is applicable to tobacco products. FDA has issued guidance interpreting SE within the meaning of section 910 of the FD&C Act.

C. Comments on the Grandfather Date

We received numerous comments on the February 15, 2007, grandfather date and the challenges it may present to certain categories of the newly deemed products. We address those comments as follows.

Lack of Authority To Change the Grandfather Date to a Later Date. As stated in the NPRM, FDA has determined that it lacks authority to change the grandfather date, which is set by statute (79 FR 23142 at 23174). FDA specifically asked for comments on our legal interpretation. We received a large number of comments in response to this statement, but none provided a legal theory that would support changing the date.

(Comment 19) A number of comments argued that adoption of a later grandfather date would be an acceptable exercise of FDA's discretion under section 701(a) of the FD&C Act, which provides FDA authority to issue regulations "for the efficient enforcement" of the statute. Others argued that an alternative date would be a permissible Agency interpretation of the statute, subject to deference under the *Chevron* doctrine. (See *Chevron U.S.A., Inc.* v. *NRDC,* 467 U.S. 837 (1984).)

(Response) After careful consideration of these comments, FDA concludes that it lacks authority to change the grandfather date for the newly deemed products. The grandfather date is prescribed in the statute. Section 910(a)(1)(A) of the FD&C Act states, in pertinent part, that the term "new tobacco product" means any tobacco product (including those products in test markets) that was not commercially marketed in the United States on February 15, 2007. For purposes of the SE pathway, the statute also clearly states that a predicate product must be commercially marketed (other than for test marketing) in the United States on February 15, 2007, in both section 910(a)(2)(A) and section 910(j)(1). FDA's authority is not so broad as to allow FDA to issue a regulation that contradicts a clear statutory provision.

Many comments cited examples of FDA's exercise of discretion to show that FDA can and should exercise discretion to change the grandfather date. For example, comments pointed to FDA's decision to extend compliance deadlines, as well as FDA's guidance informing industry that it does not intend to take enforcement action against manufacturers who make tobacco blending changes without a premarket submission for a new tobacco product when such tobacco blending changes are intended to address the natural variation of tobacco (*e.g.*, tobacco blending changes due to variation in growing conditions). However, the exercise of discretion reflected in these examples did not require FDA to contradict the clear language of the Tobacco Control Act, as changing the grandfather date would.

(Comment 20) A number of comments argued that the February 15, 2007, date in section 910 of the FD&C Act is simply an anachronism, that the date was only intended to apply to the initially regulated products, and the fact that the statutory language does not provide a different date is simply a drafting error.

(Response) FDA disagrees and is aware of no evidence supporting this view. Congress carefully distinguished those provisions of the statute that would apply to all tobacco products from those that would apply only to the initially regulated products or, in some cases, only to traditional cigarettes. (See, *e.g.*, section 102(a)(1) of the Tobacco Control Act (requiring FDA to issue a rule establishing restrictions on the sale and distribution of cigarettes and smokeless tobacco, with certain different provisions for the two categories of products).) If Congress had intended that there be a later grandfather date for tobacco products deemed subject to the statute after its date of enactment, it would have provided one.

(Comment 21) Some comments argued that application of the February 15, 2007, date is unfair to the manufacturers of the newly deemed tobacco products (particularly e-cigarettes) because they were not on notice of pending regulation and they contended that "all newly deemed products will be forced from the market." Thus, they argue, decisions were made to invest in an industry that was presumed to be unregulated, and now the industry must bear unanticipated costs.

(Response) FDA disagrees with comments stating that all newly deemed products will be forced to be removed from the market as some newly deemed products will qualify as "grandfathered" products under the statute and any that are not grandfathered will be able to apply for premarket authorization. The Tobacco Control Act plainly provides for regulation of all tobacco products. FDA also clearly stated its intention to deem these products long before the NPRM was published (see Unified Agenda, Spring 2011, RIN 0910–AG38). Therefore, manufacturers of the newly deemed products have been on notice for more than 4 years that these products could and likely would be regulated.

The ENDS industry has acknowledged that it was aware of both FDA's intention to regulate ENDS and the applicability of the Tobacco Control Act to e-cigarettes and other ENDS, as evidenced by the litigation in *Smoking Everywhere, Inc.* v. *Food & Drug Administration,* 680 F. Supp.2d 62 (D.D.C. 2010), affirmed by *Sottera, Inc.* v. *Food & Drug Administration,* 627 F.3d 891 (D.C. Cir. 2010), which was pending during the passage of the Tobacco Control Act. When FDA attempted to regulate e-cigarettes as a drug-device combination, plaintiffs Sottera (doing business as NJOY) and Smoking Everywhere argued that Congress intended for tobacco products, including their own, to be subject to the Tobacco Control Act and not to the drug and device provisions of the FD&C Act. The district court described plaintiffs' position as follows: "In *FDA* v. *Brown and Williamson Tobacco Corp.*, the Supreme Court held that tobacco products, like traditional cigarettes, are not subject to FDA regulation as a drug or device. [529 U.S. 120 (2000).] Because electronic cigarettes, as marketed by plaintiffs, are the functional equivalent of traditional cigarettes, plaintiffs contend that FDA cannot regulate their products [as combination drug-device products]. They further contend that Congress's recent enactment of the [Tobacco Control Act] supports their argument. Under the [Act], FDA may now regulate tobacco products, which the Act defines as "any product made or derived from tobacco that is intended for human consumption," . . . but it cannot regulate those products as it would a drug or device under the FDCA[.] There being no dispute that the nicotine in plaintiffs' electronic cigarettes is naturally distilled from actual tobacco and is intended for human consumption, . . . plaintiffs assert that their electronic cigarettes qualify as a tobacco product and are therefore exempt from regulation as a drug-device combination." (*Smoking Everywhere* v. *FDA,* 680 F. Supp. 2d 62, 66–67 (D.D.C. 2010).)

The district court found that, "it is apparent from Congress's broad definition of 'tobacco product' that it intended the Tobacco Act's regulatory scheme to cover far more than the fixed array of traditional tobacco products[.]" (Id. at 71.) ENDS manufacturers were made especially aware of FDA's authority to deem their products and subject them to the tobacco control authorities of the FD&C Act when the court noted that ". . . now that FDA has regulatory power over electronic cigarettes through the Tobacco Act, any harm to the public interest or to third parties caused by an injunction that merely forbids FDA from regulating electronic cigarettes as a drug-device combination is greatly diminished." (Id. at 77–78.)

On appeal, the D.C. Circuit affirmed, commenting that "the Tobacco Act provides the FDA with regulatory authority over tobacco products without requiring therapeutic claims. . . . [T]he act broadly defines tobacco products as extending to 'any product made or derived from tobacco.' " Sottera, Inc. v. Food & Drug Administration, 627 F.3d 891, 897 (D.C. Cir. 2010) (quoting 21 U.S.C. 321(rr)(1); emphases added by the court). The D.C. Circuit went on to state that "the [lower] court rightly found that the FDA has authority under the Tobacco Act to regulate electronic cigarettes"—authority that, it added, was "unquestioned." *Id.* at 898.

(Comment 22) Some comments argued that FDA previously exercised enforcement discretion to amend the grandfather date of the reissued 1996 rule (published in the **Federal Register** of August 28, 1996, 61 FR 44396) with respect to use of a trade or brand name of a nontobacco product for cigarettes or smokeless tobacco products and argued that FDA has the authority to take similar action with respect to the SE grandfather date.

(Response) FDA disagrees. In section 102 of the Tobacco Control Act, Congress required FDA to reissue the 1996 final rule regarding cigarettes and smokeless tobacco identical to the original rule (61 FR 44396 at 44615 through 44618), with certain enumerated exceptions. Congress did not list the grandfather date for the use of nontobacco brand-names as one of the exceptions. Nonetheless, the Agency issued a compliance policy stating that it did not intend to enforce the January 1, 1995, grandfather date for the use of a nontobacco brand name while considering what changes to the regulation, if any, would be appropriate. Section 102(a)(4) also gave FDA authority to amend its own rule. On November 17, 2011, FDA issued the proposed brand name rule (76 FR 71281) seeking to exercise its authority to amend the January 1, 1995, date that was originally included in 21 CFR 897.16(a) to June 22, 2009, in recognition of the fact that 14 years elapsed since the publication of the 1996 final rule. Using the January 1995 date would have significantly changed the provision, from one that was intended to apply prospectively to one that applies retroactively. The statute does not give FDA similar authority to change the provisions in section 910 of the FD&C Act to amend the grandfather date.

D. Impact of Premarket Requirements

(Comment 23) Numerous comments argued that if the SE pathway is not available for some newly deemed products, manufacturers will have to use the PMTA pathway, will not have sufficient resources to complete PMTAs, and will be forced to remove their products from the market. Members of the e-cigarette industry further argued that removal of their products would be detrimental to public health. However, other comments expressed concern regarding any delay in implementing and enforcing the premarket review requirements given the data showing the growing use of the newly deemed products, particularly among youth and young adults.

(Response) As an initial matter, FDA notes that the primary premarket pathway for new tobacco products is the premarket tobacco product application pathway, and that the SE and SE exemption pathways are exceptions to that pathway, but manufacturers can choose to submit applications under any of the three pathways for which they think they can meet the criteria in the FD&C Act for marketing authorization for a new product. See section 910(a)(2)(A) of the FD&C Act stating that an order for a new tobacco product is required unless the Secretary has issued an order that the tobacco product is substantially equivalent to tobacco product commercially marketed. The SE pathway is not intended to be available to every product. Rather, by its terms, the SE pathway is limited to products that can be shown to be substantially equivalent to a product that was on the market on the grandfather date. If that showing cannot be made, the appropriate premarket pathway is the premarket tobacco product application pathway.

To obtain marketing authorization under the PMTA pathway, manufacturers are required to establish, among other things, that permitting their products to be marketed would be appropriate for the protection of public health. In establishing this, manufacturers should take into account, and FDA will consider, the ways in which the new product is likely to be used. We also note that, elsewhere in this issue of the **Federal Register**, FDA has made available draft guidance, which when final will describe FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products. Should firms have specific questions regarding application content and information necessary to satisfy the filing criteria under section 910(b) or ways to reduce burden by reference to another submission, they may contact CTP's OS at 1–877–CTP–1373.

For example, where a manufacturer seeks authorization of a new e-liquid to be used with ENDS, the manufacturer may need to provide evidence and analysis of the product's likely impact when used in the range of delivery systems available. Similarly, a manufacturer seeking authorization of a stand-alone apparatus component—such as a heating coil or cartridge—may need to provide evidence and analysis of the product's likely impact when used together with the range of other components and liquids available.

In the case of e-liquids, FDA expects that it may be possible for manufacturers to satisfy the statute by demonstrating that marketing of the liquid is appropriate for the protection of public health as it may be used in any of the legally available delivery systems. While FDA recognizes that there may remain some degree of uncertainty in any such analysis, FDA expects that the range of delivery system specifications authorized by FDA will provide a sufficiently specific spectrum of possibilities, such that a meaningful public health impact analysis can be done.

In the case of ENDS hardware/apparatus components, FDA expects that it may be difficult for manufacturers to make the showing necessary to meet the statutory standard, given the great extent of possible variations in combinations of hardware components, if all are considered and sold separately. Thus, with respect to apparatus, FDA expects that manufacturers will be most successful where authorization is sought for entire delivery systems, rather than individual components. In the case of these complete delivery systems—systems for which the application covers all potential parts, including customizable options as applicable, and where labeling, instructions for use and/or other measures are used to help ensure use as intended—FDA expects that the range of possible outcomes may be narrow enough for the manufacturer to demonstrate, and for FDA to assess, public health impact.

FDA also notes that many comments from the ENDS industry emphasized the potential public health benefits of these products in their comments on the NPRM. For example, numerous industry comments argued that restrictions on access to the newly deemed products would be detrimental to public health, as the products may be less toxic than conventional cigarettes and may be successfully used as a cessation product. FDA's consideration of public health benefits of products will be included in FDA's review of PMTAs based on the evidence.

(Comment 24) A few comments expressed concern that if manufacturers would be forced to submit PMTAs rather than SE applications, they would need to conduct more animal studies to meet PMTA requirements.

(Response) FDA shares an interest in reducing the reliance on animal-based studies, and the Agency is committed to the three "Rs" of reduction, refinement, and replacement in animal testing. Although we are hopeful that in vitro assays and computer models can ultimately help to replace much of the need for animal testing, there are still many areas for which non-animal testing is not yet a scientifically valid and available option. FDA is committed to addressing concerns raised regarding use of animal testing methods, while still ensuring that the Agency satisfies its public health and patient safety responsibilities and acts in accordance with its governing statutes.

(Comment 25) One comment stated that e-cigarettes have two variables—the ratio of the propylene glycol to vegetable glycerin and the level of nicotine in the product—which would result in many combinations and, therefore, require submission of numerous, very costly PMTAs for products that have very minor variations. In contrast, one comment noted that the lower number of ingredients in e-cigarettes means that less information will be required in PMTAs for e-cigarettes than for other products.

(Response) The requirements and costs of a PMTA may vary based on the type and complexity of the product. Variations in the ratio of ingredients, such as propylene glycol and glycerin, would indicate that products have different levels of each of these ingredients. As stated in section 910(a)(1)(B) of the FD&C Act, any change in an ingredient level, as with additions or removal of ingredients, yields a new tobacco product.

We also note that the statute requires FDA to review PMTAs based on well-controlled investigations, "when appropriate," or other valid scientific evidence sufficient to evaluate the tobacco product. In addition, elsewhere in this issue of the **Federal Register**, FDA has made available draft guidance, which when final will describe FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products. Should firms have specific questions regarding application content and information necessary to satisfy the filing criteria under section 910(b) or ways to reduce burden by reference to another submission, they may contact CTP's OS at 1–877–CTP–1373.

(Comment 26) Many comments stated that a requirement to prepare PMTAs for all of the many parts and components that go into some of the newly deemed tobacco products would create an effective ban of these products.

(Response) The definition of a tobacco product includes components and parts, and these products are subject to the automatic provisions of the FD&C Act, including premarket authorization requirements. However, at this time, FDA intends to limit enforcement of the premarket authorization provisions to finished tobacco products. In this context, a finished tobacco product refers to a tobacco product, including all components and parts, sealed in final packaging intended for consumer use (*e.g.*, filters or filter tubes sold separately to consumers or as part of kits). For example, an e-liquid sealed in final packaging that is to be sold or distributed to a consumer for use in a finished tobacco product will be subject to enforcement if it is on the market without authorization. In contrast, an e-liquid that is sold or distributed for further manufacturing into a finished ENDS product is not itself a finished tobacco product. At this time, FDA does not intend to enforce the premarket authorization requirements against such e-liquids or other components and parts of newly deemed products that are sold or distributed solely for further manufacturing without a marketing order.

(Comment 27) Many expressed concern that requiring cigars to comply with the PMTA requirements would either force cigars off the market or require them to mimic cigarettes in uniformity of size, shape, and taste, which would change the fundamental nature of the cigar industry. At least one comment stated that FDA should eliminate the premarket and SE application requirements for cigars and instead implement a system by which cigar manufacturers could introduce new products to the market after providing 90 days' notice to FDA of their intentions to do so.

(Response) FDA disagrees. Sections 905 and 910 of the FD&C Act establish specific requirements that apply to new tobacco products before they may be marketed. Some cigars may be grandfathered and other products may have valid predicate products and may be able to avail themselves of the SE pathway to market. FDA generally expects that cigars with blending changes (other than blending changes to address the natural variation of tobacco, FDA's policy for which is discussed in the response to Comment 28) will be able to successfully use the SE pathway so long as the blending change does not significantly raise levels of HPHCs in the product (*i.e.*, raising different questions of public health). If a product is unable to utilize the SE pathway and is not eligible for an SE exemption, the statute requires the product (including limited or seasonal blends) to obtain a marketing authorization through the PMTA pathway. As explained previously, the requirements of a particular PMTA may also vary based on the type and complexity of the product. If an applicant wishes to discuss a product application, the applicant may request a meeting as set forth in FDA's final guidance entitled "Meetings with Industry and Investigators on the Research and Development of Tobacco Products" (announced May 25, 2012, 77 FR 31368).

(Comment 28) A number of comments discussed the natural variability in the tobacco used for cigars and pipe tobacco, stating that because the characteristics of tobacco used for each of these products can vary from year to year, manufacturers must use different blends to create a consistent product. Some comments expressed concerns that each blending change could result in a new product for which manufacturers and importers would be required to submit a PMTA. They also stated that this would be economically unfeasible for limited editions and special releases for cigars and pipe tobacco. Others expressed concerns that tobacco blending changes and natural variations of the tobacco used in the product, such as the number of ribs or perforations in a cigar wrapper, may produce different results for HPHC testing of the same product. These comments advocated that cigars and pipe tobacco should be either excluded from the ingredient listing, HPHC listing, and premarket review requirements or manufacturers should be allowed to make tobacco blending changes without being required to submit a marketing application or comply with HPHC testing and reporting requirements.

(Response) FDA is aware that the tobacco used to produce some of the newly deemed products can naturally vary from year to year. As stated in section IV.C.1, FDA does not intend to enforce the premarket authorization requirements where manufacturers make tobacco blending changes without premarket authorization for tobacco blending changes to address the natural variation of tobacco (*e.g.*, tobacco blending changes due to variation in growing conditions) in order to maintain a consistent product. However, FDA does intend to enforce the premarket authorization requirement for tobacco blending changes that are intended to alter the chemical or perception properties of the new product (*e.g.*, nicotine level, pH, smoothness, harshness, etc.) compared to the predicate product, and such changes should be reported under 910 or 905(j). In addition, FDA intends to issue a guidance regarding HPHC reporting under section 904(a)(3), and later a testing and reporting regulation as required by section 915, with enough time for manufacturers to report given the 3-year compliance period for HPHC reporting. As noted elsewhere in this document, FDA does not intend to enforce the reporting requirements under section 904(a)(3) for newly deemed products before the close of the 3-year compliance period, even if the HPHC guidance is issued well in advance of that time. Additionally, changes made to the number of ribs or perforations in a cigar wrapper as well as any changes to ingredients or additives, would result in a new tobacco product (as stated in section 910(a)(1)(B)) and would require a marketing application and authorization under section 910 or 905(j). FDA intends to enforce other applicable requirements (*e.g.*, ingredient listing) against manufacturers making blending changes to address the natural variation of tobacco.

(Comment 29) Some comments stated that small companies are at a competitive disadvantage compared to larger companies because they do not have the resources to complete PMTAs. They feared that FDA's premarket requirements would force many companies to remove their products from the market and that, as a result, cigarette use would increase. To address these concerns, comments suggested that FDA stagger requirements based on the size of the business to protect small businesses and spur innovation. They stated that staggered compliance periods could be based on the number of employees in the business, number of products the business has, and/or the product's placement on the continuum of risk. In addition, some comments stated that such staggered dates could be based on FDA's issuance of final PMTA guidance for each product category, which would allow for more meaningful and complete submissions. They also stated that, because such guidance likely would include issues of first impression, the Agency is required to first issue the guidance in draft form before issuing a final guidance. Some comments stated that staggered PMTA compliance periods may not be sufficient to address the competitive disadvantage of small companies because they still would not have the resources to complete a PMTA for each of their new tobacco products.

Other comments believed that premarket requirements should apply equally to all manufacturers, regardless of size, for several reasons. First, they explained that the FD&C Act states that the purpose of a PMTA is to ensure that permitting marketing of a tobacco product would be "appropriate for the protection of the public health" (section 910(c)(2)(A)) and that this public health purpose should outweigh concerns regarding small businesses. The comments noted that the public health purpose of the Tobacco Control Act does not differentiate between large and small businesses. Second, they stated that the public health concerns presented by products of small manufacturers are no less significant than the public health concerns presented by products of large manufacturers. They also noted that small manufacturers may lack the quality control processes that they believed large manufacturers already have in place. They also noted that many small businesses are e-cigarette retail establishments that mix their own e-liquids, which can be accessible to children and potentially subject to tampering and, therefore, should not receive additional time to comply with critical automatic requirements. Third, they stated that Congress did not intend for small manufacturers to have additional time to comply with all of the automatic provisions under the law once they are deemed. Instead, Congress only intended that small manufacturers receive additional time to comply with good manufacturing practices under section 906(e)(1)(B) of the FD&C Act and testing requirements under section 915(d) (21 U.S.C. 387o). If Congress had intended for small manufacturers to receive additional time to comply with other provisions, it would have explicitly said so. Fourth, they stated that FDA already provides adequate assistance to small businesses with the small business center (included as part of CTP's OCE) and frequent Webinar programs, but other comments stated that the small business center was not properly organized and staffed.

(Response) FDA is announcing multiple policies with this final rule including a policy for "small-scale tobacco product manufacturers" discussed in section IV.D. FDA is announcing this policy, because "small-scale tobacco product manufacturers" do not have the same business capabilities of larger businesses. Moreover, FDA did not receive any comments from large manufacturers suggesting that they are in need of the relief that is being provided for small-scale tobacco product manufacturers. Congress also acknowledged the potential disparity by requiring FDA to establish the Office of Small Business Assistance (OSBA) within CTP to assist small tobacco product manufacturers and retailers in complying with the law. OSBA is available to assist manufacturers with any questions regarding statutory and regulatory requirements and will continue to provide support with respect to these newly finalized regulations. Small business owners may contact the OSBA by calling 1–877–CTP–1373 or sending a message to *SmallBiz.Tobacco@fda.hhs.gov*. FDA intends to expand the staffing for the OSBA to provide support for manufacturers who are newly regulated by FDA.

As discussed in the earlier section of this final rule describing the purpose of this rule, FDA will be able to obtain critical information regarding the health risks of newly deemed tobacco products, including information derived from ingredient listing submissions and reporting of HPHCs. Because FDA did not previously have regulatory authority over these products, it does not have access to commercial confidential information on materials, ingredients, design, composition, heating source and other features of these products. As FDA gains experience regulating these newly deemed tobacco products, the Agency expects there will be more information to aid manufacturers seeking premarket determination that a tobacco product is "appropriate for the protection of public health." However, it would negatively impact public health if FDA were to significantly delay implementation of its premarket requirement authorities after issuance of this deeming rule. Such delay could result in more youth becoming addicted to nicotine. FDA recognized that ENDS are different than conventional tobacco products, and that more specific guidance would be useful to manufacturers in preparing premarket applications. Therefore, FDA has made available draft guidance, which when final, will describe FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products, including recommendations that would help to support a showing that the marketing of a product is appropriate for the protection of public health. FDA intends to issue additional guidance in the future.

E. Clinical Studies and PMTAs

(Comment 30) Comments expressed concern about the need for costly clinical studies to develop PMTAs that satisfy the requirements under section 910 of the FD&C Act. They indicated that FDA's previous statements, including language from draft guidance that recommends the collection of numerous types of data ranging from chemistry to in vivo toxicology and possible clinical trials, suggest the need for costly studies that are redundant and unnecessary. They also noted the Government Accountability Office's (GAO's) summary of this issue, which stated "CTP's guidance document for the PMTA pathway states that PMTA submissions should include data from well-controlled studies demonstrating that the tobacco product is appropriate for the protection of the public health. [According to CTP,] '[d]ata from such studies must address, for example, the health risks associated with the product in comparison to the health risks of other products on the market and the product's effect on the likelihood that current tobacco users will stop using tobacco products'" (Ref. 41 at 18–19).

(Response) In the NPRM, FDA included discussion intended to supplement and clarify its earlier statements regarding clinical studies needed for PMTAs (79 FR 23142 at 23176 and 23177). As we noted, FDA expects that, in some cases, it may be possible for an applicant to obtain a PMTA marketing authorization order without conducting any new nonclinical or clinical studies where there is an established body of evidence regarding the public health impact of the product. However, in cases where there have been few or no scientific studies of a product's potential impact on the public health, new nonclinical and clinical studies may be required for market authorization. In addition, elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a draft guidance, which when final will provide the Agency's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products, including the need for "clinical studies" for the purposes of preparing PMTAs for ENDS.

(Comment 31) Several comments suggested that section 910(c)(5)(B) provides FDA with authority to develop a flexible framework for PMTAs that would not require well-controlled investigations. They suggested the following alternatives to the requirement of well-controlled investigations:

- Create a user registry for e-cigarette users to input baseline demographic, cessation and initiation, adverse experiences, and followup data for collection of real-world data;
- Identify clinical studies that will constitute "valid scientific data" and identify historical controls and published literature suitable for comparative purposes;
- Adopt a process similar to FDA's process for new medical devices, where the product can undergo de novo review to obtain a lower risk classification and be subject to general controls and specific controls (rather than the premarket requirements under sections 905 and 910(d));
- Use a process similar to the accelerated approval process for new drugs for serious or life-threatening illnesses, which bases approval on the effect of the drug on a surrogate endpoint; and
- Adopt a method similar to the dietary supplement process, based on registration, ingredient disclosures, and good manufacturing practice (GMP) compliance checks.

(Response) FDA is not implementing these changes. Most of the approaches in the comments are all implemented under different statutory authorities that do not apply to tobacco products. FDA's responses to these individual suggestions are discussed in the following paragraphs.

- Create a user registry for e-cigarette users to input baseline demographic, cessation and initiation, adverse experiences, and follow-up data for collection of real-world data—

The data and information in a PMTA must be sufficient to show that the marketing of the *specific* new tobacco product is "appropriate for the protection of the public health" (section 910(c)(4) of the FD&C Act). This information from a user registry would not be sufficient on its own to support a marketing application, but it could provide additional real-time information (*e.g.*, adverse experiences that may otherwise be gathered in more long-term studies). If an applicant wishes to use a registry or other alternatives, we encourage it to request a meeting with FDA to discuss these and other issues *before* it prepares and submits an application.

- Identify clinical studies that will constitute "valid scientific data" and identify historical controls and published literature deemed suitable for comparative purposes—

FDA does not have enough information at this time to do this in a manner that would be generally applicable. It may be possible for an applicant to submit information (*e.g.*, published literature, marketing information) with appropriate information or data that would be adequate scientific data for parts of the application. This will likely be limited to specific aspects of the PMTA requirements (*e.g.*, nonclinical work, shelf life/stability, health risks based on consumer information). If an applicant wishes to use this or other alternatives, we encourage them to request a meeting with FDA to discuss these and other issues in the context of a particular product before they prepare and submit an application.

- Adopt a process similar to FDA's process for new medical devices, where the product can undergo de novo review to obtain a lower risk classification and be subject to general controls and specific controls (rather than the premarket requirements under sections 905 and 910(d))—

FDA is not authorized to deviate from the premarket requirements of chapter IX of the FD&C Act. The medical device requirements in chapter V of the FD&C Act apply to medical devices only, not tobacco products as defined in section 201(rr) of the FD&C Act.

- Use a process similar to the accelerated approval process for new drugs for serious or life-threatening illnesses, which bases approval on the effect of the drug on a surrogate endpoint—

The purpose of the accelerated drug approval process was to establish procedures designed to expedite the development, evaluation, and marketing of new therapies intended to treat persons with life-threatening and severely debilitating illnesses, especially where no satisfactory alternative therapy exists. This is not the case with a tobacco product. Section 910(b) of the FD&C Act requires that specific contents be contained in a PMTA. In addition, as stated in section 910(c)(4) of the FD&C Act, the data and information in a PMTA must be sufficient to show that the marketing of a new tobacco product is "appropriate for the protection of the public health." FDA believes that an accelerated premarket review process is neither feasible nor appropriate for these products at this time. However, if an applicant believes it can demonstrate that its new product is "appropriate for the protection of public health" in an accelerated fashion, we encourage it to request a meeting with FDA to discuss these and other issues before they prepare and submit an application.

- Adopt a method similar to the dietary supplement process, based on registration, ingredient disclosures, and GMP compliance checks—

As stated in section 910(c)(4) of the FD&C Act, the data and information in a PMTA must be sufficient to show that the marketing of a new tobacco product is "appropriate for the protection of the public health." The method suggested in this comment would differ from the process and standard outlined in sections 905 and 910 of the FD&C Act and, therefore, is inapplicable to tobacco products.

The FD&C Act states that determining whether a new product is appropriate for the protection of the public health shall be determined "when appropriate . . . on the basis of well-controlled investigations." (section 910(c)(5)(A)). However, section 910(c)(5)(B) of the FD&C Act also allows the Agency to consider other "valid scientific evidence" if found sufficient to evaluate the tobacco product. Thus, if an application includes, for example, information (*e.g.*, published literature, marketing information) with appropriate bridging studies, FDA will review that information to determine whether it is valid scientific evidence sufficient to demonstrate that the product is appropriate for the protection of the public health. If an applicant has questions or other alternatives to well-controlled investigations it would like to utilize, we recommend that it meet with FDA to discuss the approach prior to preparing and submitting an application (see FDA guidance entitled "Meetings with Industry and Investigators on the Research and Development of Tobacco Products"). We also note that, elsewhere in the **Federal Register**, FDA is announcing the availability of a draft guidance, which when final will provide the Agency's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products.

F. Premarket Pathways and Continuum of Risk

(Comment 32) We received many comments requesting that FDA provide an expedited or abbreviated pathway for those products that are on the less harmful end of the continuum of risk spectrum. Some comments stated that noncombusted and nicotine delivery products derived from, but not containing, tobacco should be treated differently than combusted products for the purposes of premarket review and that less harmful products need an accelerated pathway to ensure continued innovation. They also stated that the different risks and benefits associated with tobacco derived nicotine delivery products make the PMTA process and FDA's draft PMTA guidance inapplicable. Other comments claimed that e-cigarettes and other tobacco derived nicotine delivery products are not tobacco products at all and do not fit into the strict tobacco product regulatory framework. The comments also stated that an abbreviated pathway should be based on public participation to decide what information is sufficient to determine that the product is appropriate for the protection of the public health without impeding innovation.

Some comments also suggested that FDA require a premarket notification or report, similar to EU's Tobacco Products Directive, where the notification certifies that the product has met specific product standards, and the Agency could approve the product based on the certification.

At least one comment disagreed with the idea of providing an expedited or abbreviated pathway for some products, stating that FDA will not know if the products are less harmful until it reviews the applications.

(Response) An ENDS is a tobacco product as long as it meets the definition of "tobacco product" under section 201(rr) of the FD&C Act. Regardless of the type of tobacco product (and its potential risks and benefits), *all* tobacco products going through the PMTA pathway must meet all the requirements for a premarket authorization in section 910 of the FD&C Act before FDA can issue such an authorization. In addition, we note that, at this time, while there is general evidence of harm for all classes of newly deemed products, FDA has not yet obtained product-specific evidence regarding the various ENDS on the market. Since ENDS products contain nicotine, it is possible that such products may result in overall public health harm if individuals who would not have initiated tobacco use in the absence of ENDS ultimately graduate to combusted products (though scientific data regarding this hypothesis is unclear) or use them in conjunction with combusted products or if the users would never have initiated tobacco use absent the availability of ENDS. In addition, nicotine use in any form is of particular concern for youth and pregnant women. On the other hand, if ENDS promote transition from combustible tobacco use among current users, there could be a public health benefit. The 2014 Surgeon General Report notes that "[f]urther research with attention to their individual and population-level consequences will be helpful to fully address these questions. However, the promotion of noncombustible products is much more likely to provide public health benefits only in an environment where the appeal, accessibility, promotion, and use of cigarettes and other combusted tobacco products are being rapidly reduced" (Ref. 9 at 873). FDA believes that regulation of all tobacco products will help to address these questions and provide public health benefits.

(Comment 33) Many comments expressed concern regarding the cost of PMTAs for newly deemed products and the effect that this requirement will have on cigarette smokers who are attempting to quit. They also disagreed with FDA's assertion that premarket review will enhance innovation (79 FR 23142 at 23149), stating that the cost of submitting PMTAs is more of a business concern than competition with lower quality products. They claimed that the PMTA process would have the largest negative impact on open system apparatus, which some comments believed are the most popular with people who have achieved complete substitution from conventional cigarettes to e-cigarettes. The comment suggests that the result would be that newer e-cigarettes would not make it onto the market, driving up prices, and driving adult consumers back to conventional cigarettes.

(Response) The Tobacco Control Act provides for three specific marketing pathways for new tobacco products—SE., SE exemption, and PMTA; it does not provide alternative pathways. Through the PMTA pathway, FDA will ensure that only products that are shown to be appropriate for the protection of public health are permitted to be marketed. Use of the PMTA pathway also will allow FDA to monitor product development and changes and to prevent more harmful or addictive products from reaching the market. The PMTA pathway will incentivize development of tobacco products that pose less risk to human health by limiting market access for more-risky competitor products. Furthermore, since the "appropriate for the protection of the public health" standard involves comparison to the general tobacco product market existing at the time of an application, FDA believes that, over time, the premarket authorities will move the market toward less-risky tobacco products.

A recently published paper by Friedman (Ref. 42) looked at youth smoking rates in states that enacted early bans on sales of e-cigarettes to minors. The author concluded, based on state-level combusted cigarette smoking data available through 2013, that the decline in adolescent smoking rates slowed in states that enacted restrictions on access to ENDS by minors before January 2013, relative to states that did not. Some have interpreted the results of the study as providing evidence that any policies that restrict access to e-cigarettes or regulate e-cigarettes could increase consumption of combusted tobacco products. However, the research has several limitations that are acknowledged in the study. First, the survey data used in the study, from the NSDUH, track changes in the prevalence of cigarette smoking but lack information available on e-cigarette use. As such, the study does not establish that youth switched directly from using ENDS to smoking combusted cigarettes after restrictions on sales of e-cigarettes to minors were enacted, only that the decline in prevalence of cigarette smoking slowed in states where such restrictions were enacted relative to states that did not. Second, the fact that the study examines a period very early on in the development of the market for ENDS products may also limit the inferences that can be drawn for substitution and dual usage patterns that will emerge as the market matures. Third, the "increase" in the prevalence of youth smoking is relative to what would have been predicted from ongoing trends; in both states that did and states that did not enact restrictions, the prevalence of youth smoking continued to decline, just at a slower rate in the states that enacted bans. Finally, given these issues, FDA acknowledges this paper as a first attempt to study potential impacts of youth ENDS access restrictions, but more research will be necessary to explore the potential effects of this rule on product switching or dual usage.

(Comment 34) Some comments suggested that FDA should establish a monograph-like system to allow e-cigarettes seeking to enter the market to be compared to a baseline or "model" e-cigarette. In addition, a few comments suggested that combustible product manufacturers should also be able to compare their products to a reference product to ease SE burdens.

(Response) FDA disagrees as these suggested alternatives are not consistent with the Tobacco Control Act. Under the SE pathway, FDA must determine if the new tobacco product raises different questions of public health than an identified, and valid, predicate product. To be an eligible predicate product under section 910 of the FD&C Act, the product must have been commercially marketed in the United States on February 15, 2007, or been previously found substantially equivalent.

Moreover, elsewhere in this issue of the **Federal Register**, FDA has made available a final guidance to provide information for manufacturers on how to establish and reference a Tobacco Product Master File (TPMF). We expect reliance on TPMFs to increase efficiency and reduce any burdens on manufacturers. As discussed in section IX, because of the nature of upstream supply of many components for ENDS products, especially e-liquids, FDA anticipates that commercial incentives will be sufficient to drive manufacturer reliance on the system of master files. We note that, at present, FDA understands that, based on the Agency's review of publically available data, the number of entities engaged in upstream production of liquid nicotine and flavors specifically developed for use with e-liquids is small. Specifically, based on internet searches and information provided on firm Web sites, FDA estimates that there are roughly five to ten major pure liquid nicotine suppliers, most of which claim to have a significant market share.[10] Several of these companies already have master files with FDA for their nicotine products or report that they are ready to file submissions to meet U.S. and EU regulatory requirements. An online search of flavor manufacturers revealed many suppliers of flavorings that can be added to food or other consumer products; any of these products potentially could be used as e-liquid flavoring. However, FDA searches identified only two to three flavor houses that make flavoring specifically for e-liquids.[11] Given these realities of the marketplace, FDA expects that the master file system will be widely appealing and widely utilized by the ENDS industry.

(Comment 35) Comments suggested that the "appropriate for the protection of the public health" standard for PMTAs was meant for those products with well-established risks to consumers and should not apply to e-cigarettes. They suggested that FDA establish a different standard for issuing PMTA orders for e-cigarettes (*i.e.,* that the product is no more hazardous than currently marketed tobacco products).

(Response) FDA disagrees with comments suggesting the use of a different standard for e-cigarettes and other ENDS. Section 910(c)(4) specifies the standard FDA is to apply in deciding whether to issue a PMTA marketing authorization order. That section states that the product must be "appropriate for the protection of the public health" which "shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account—(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and (B) the increased or decreased likelihood that those who do not use tobacco products will start using such products." FDA is not authorized to deviate from this statutory standard.

(Comment 36) Some comments recommended that FDA deem products currently on the market without subjecting those products to the statute's premarketing requirements. Similarly, some comments argued that the premarket requirements should not apply to specific categories of products (specifically, e-cigarettes and other novel tobacco products), including those that are introduced after the enactment of the rule. They stated that this large burden does not have a clear benefit to public health.

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[10] See, *e.g.,* Ref. 43. FDA Internet searches included review of Web sites identifying product suppliers, such as *www.thomasnet.com* and *www.alibaba.com,* as well as manufacturer Web sites and news reports on the market.

[11] FDA Internet searches included review of Web sites identifying product suppliers, such as *www.thomasnet.com* and *www.alibaba.com,* as well as manufacturer Web sites and news reports on the market.

(Response) The statute automatically subjects deemed products to the statutory requirements for "tobacco products" in chapter IX of the FD&C Act. Once deemed, the products are subject to all statutory provisions that apply to all tobacco products covered by the FD&C Act. See section 901(b) of the FD&C Act ("This subchapter shall apply to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary by regulation deems to be subject to this subchapter."). Section 910, which establishes the procedures that must be followed before a new tobacco product can be authorized for marketing, is one of the statutory provisions that apply automatically to all tobacco products, including newly deemed products. FDA believes that the premarket review requirements will, in fact, benefit public health, as discussed in the NPRM (79 FR 23142 at 23148 and 23149).

(Comment 37) Some comments stated that FDA must get a better scientific understanding of e-cigarettes before finalizing the compliance period for premarket review of these products. One comment also proposed a system in which FDA could create product standards under section 907 of the FD&C Act for the entire category of e-cigarettes and then approve or reject PMTAs for individual e-cigarettes based upon whether they meet the standards.

(Response) FDA disagrees with comments suggesting that the Agency needs additional time before determining an appropriate compliance period for the premarket review requirements for ENDS. As we have stated throughout the document, FDA has data regarding health harms generally associated with all of the categories of tobacco products regulated under this rule (including ENDS). FDA is regulating these products in accordance with this knowledge. FDA also disagrees with comments suggesting that FDA can change the statutory requirements and standards for issuing PMTA orders. FDA's revised compliance policy for submission of PMTAs and other premarket submissions is discussed in section V.A.

(Comment 38) At least one comment suggested that applicants be able to utilize publications regarding scientific understanding of e-cigarettes as harm reduction products to support their PMTAs.

(Response) FDA agrees that applicants can include scientific literature as part of their PMTA submission pursuant to section 910(b)(1). In addition, elsewhere in this issue of the **Federal Register**, FDA has made available draft guidance, which when final will describe FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products, including the use of scientific literature.

(Comment 39) Comments recommended that FDA issue PMTA orders based only on HPHC data and appeal to children, as well as a manufacturer's postmarketing commitments to conduct long-term studies regarding effects of e-cigarette use (similar to the supplemental application processes for new drug applications (NDA) and device premarket approval supplement regimes codified in 21 CFR 314.70 and 814.39, respectively). Comments also suggested that FDA create a supplemental PMTA for modifications and minor modifications to tobacco products so each product would not require a full PMTA.

(Response) FDA disagrees. The statutory authorities for FDA's regulation of drugs, devices, and tobacco products are different. Section 506A of the FD&C Act (21 U.S.C. 356a) authorizes FDA to utilize a supplemental NDA process allowing manufacturers to make manufacturing changes to approved drugs and section 515 (21 U.S.C. 360e) allows device manufacturers to supplement their premarket approval applications for modifications to products. Although FDA does not have the same ability to allow an applicant to obtain an authorization and later supplement the application (given the different statutory scheme for tobacco products), FDA is actively considering other opportunities for efficiency and streamlining in the PMTA process, consistent with its mission to protect the public health.

(Comment 40) One comment suggested that FDA publish guidance on how the Agency will determine whether an e-cigarette is substantially equivalent to a predicate product. According to this comment, the SE review should focus on the aerosol delivered to the consumer to determine whether a new e-cigarette raises different questions of public health.

(Response) FDA may issue guidances for specific product categories at a later date. However, FDA finds that the available guidance for SE reports should be sufficient to assist manufacturers in preparing reports and to advise them of the factors FDA considers when assessing SE reports, as evidenced by the fact that the agency has issued many orders regarding SE to applicants that have utilized the available guidance (for the most recent SE actions, see *http://www.fda.gov/TobaccoProducts/Labeling/MarketingandAdvertising/ucm435693.htm*). Previously issued SE orders were for products whose applications may differ substantially from those for the newly deemed tobacco products. As required by section 910(a)(3)(A) of the FD&C Act and as stated in FDA's guidance documents, the Agency must consider product characteristics when evaluating SE reports. The constituents found in e-cigarette aerosol are just some of the characteristics that FDA will consider when reviewing SE reports for e-cigarettes. Other characteristics include the materials, other ingredients, design, composition, heating source, and other features of the e-cigarette (see section 910(a)(3)(B)). We also encourage prospective applicants to review the applications FDA posts on *www.fda.gov* for examples of products that have different characteristics but do not raise different questions of public health when compared with the specified predicate product.

(Comment 41) Some comments provided several suggestions as to how FDA can craft the PMTA process to acknowledge the position of e-cigarettes on the continuum of nicotine-delivering products. For example, they indicated that e-cigarettes should not need to undergo a rigorous, comprehensive premarket review process and, instead, should be given an abbreviated pathway that would allow FDA to achieve the same objectives. For example, some comments suggested that, in order to streamline the process, a PMTA for an e-cigarette should be required to contain only the following: (1) A sample of the product; (2) specimens of proposed labeling; (3) a description of the product's principles of operation; (4) ingredient listing for e-liquids; (5) a description of methods of manufacturing and processing; and (6) a description of quality control and product testing systems. They suggested that FDA could require e-cigarettes to comply with product standards once they are established.

Other comments urged FDA to impose strict regulations on the sale of e-cigarettes, including extensive premarket review, to ensure that future generations are not burdened by nicotine addiction. While some of these comments noted that there may be potential benefits to some individuals, they believed the Agency cannot lower its scientific standards, weaken its requirements for rigorous science, or change its requirements for evaluating the public health impact of e-cigarettes. To determine eligibility for expedited review or an abbreviated pathway, these comments stated that FDA must recognize that: (1) The use of any tobacco product, including a well-regulated e-cigarette, poses a greater risk than using no tobacco product; and (2) the scientific evidence does not demonstrate substantial reduction in harm to an individual from e-cigarette use if the consumer dual uses with cigarettes, except when dual use is a short-term pathway to quitting smoking cigarettes.

(Response) Section 910(b) of the FD&C Act lays out the specific elements to be submitted in a PMTA and 910(c)(2)(A) specifies that FDA cannot authorize the marketing of a product where there is a lack of showing that the marketing of a new tobacco product is "appropriate for the protection of the public health." The FD&C Act states that this finding will be determined, when appropriate, on the basis of well-controlled investigations (section 910(c)(5)(A)). However, section 910(c)(5)(B) of the FD&C Act also allows the Agency to consider other "valid scientific evidence" if found sufficient to evaluate the tobacco product. Thus, if an application includes, for example, information (*e.g.,* published literature, marketing information) with appropriate bridging studies, FDA will review that information to determine whether it is valid scientific evidence sufficient to demonstrate that a product is appropriate for the protection of the public health. If an applicant has questions or other alternatives to well-controlled investigations it would like to utilize, we recommend that the applicant meet with FDA to discuss the approach prior to preparing and submitting an application (see FDA guidance "Meetings with Industry and Investigators on the Research and Development of Tobacco Products"). In addition, elsewhere in this issue of the **Federal Register**, FDA has made available ENDS PMTA draft guidance which, when final, will describe FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products.

(Comment 42) Given the differences among newly deemed product categories and the potential benefits from these products, some comments said that FDA should develop clear guidance regarding the scientific evidence the Agency will need to review the safety and health impact of these products and to accelerate the review of marketing applications where necessary.

(Response) To help provide clarity regarding submission requirements for marketing applications, FDA has issued several guidance documents, and is finalizing other guidance documents, regarding the evidence needed for SE reports, including FDA draft guidance entitled "Substantial Equivalence Reports: Manufacturer Requests for Extensions or to Change the Predicate Tobacco Product" (79 FR 41292, July 15, 2014), and FDA guidance entitled "Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007," among others. FDA also has issued a draft guidance entitled "Applications for Premarket Review of New Tobacco Products" (76 FR 60055, September 28, 2011). In addition, elsewhere in this issue of the **Federal Register**, FDA has made available draft guidance, which when final will describe FDA's current thinking on some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products. If FDA determines that additional guidance is necessary to help manufacturers prepare marketing applications, FDA will issue additional guidance and publish a notice of availability in the **Federal Register**.

(Comment 43) One comment stated that, because there is a lack of scientific evidence to show the health impact of vapor products, applying the premarket requirements to this category of products is premature. Therefore, the comment suggested that FDA exercise enforcement discretion to delay implementation of this requirement until more evidence is available.

(Response) FDA has established a compliance policy regarding the premarket review requirements. This is described in section V.A. As discussed elsewhere in this document, we believe the compliance period is appropriate, and it takes into account the time for firms to generate and submit the information for a PMTA. The requirements and costs of a PMTA may vary based on the type and complexity of the product. For example, where there is limited understanding of a product's potential impact on public health, nonclinical and clinical studies may be required for market authorization. In such case, the requirements and cost of the PMTA likely would be higher (and the review time longer) than for a product in which there is already substantial scientific data on the potential public health impact. This information provided as part of premarket review (design, ingredients, levels of HPHCs) will provide critical information on these products.

(Comment 44) One comment suggested that FDA regulate e-cigarettes as an adult consumer product without providing additional details.

(Response) It is unclear what this comment envisioned by suggesting that FDA regulate e-cigarettes as an adult consumer product. Nevertheless, FDA must regulate tobacco products in accordance with the Tobacco Control Act, including section 910 of the FD&C Act, which states that in reviewing PMTAs for new tobacco products, FDA must consider whether the marketing of such product is appropriate for the protection of the public health, and that this finding is to be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the product, taking into account—the increased or decreased likelihood that existing users of tobacco products will stop using such products; and the increased or decreased likelihood that those who do not use tobacco products will start using such products (section 910(c)(4) of the FD&C Act). This public health standard requires the Agency to consider the impact of the products on the "population as a whole," not simply the adult population that may be using such products.

(Comment 45) Some comments stated that FDA regulations should support manufacturers' efforts to invest in alternative tobacco products with the potential to reduce harm.

(Response) The Agency continues to support development of alternative tobacco products with the potential to reduce harm, and believes that the PMTA, MRTP, and other regulatory provisions will help foster the development of tobacco products that pose less risk to human health. In addition, as a practical effect of the Agency's compliance policy for premarket review of newly deemed tobacco products, FDA expects that many manufacturers, including those with alternative tobacco products, will continue to market their products during preparation of submissions and for the continued compliance period afterward. The time it takes to review premarket applications is dependent upon the type of application and the complexity of the product.

G. Other Comments

(Comment 46) A few comments suggested that FDA review and authorize marketing of products at the ingredient level. For example, if a tobacco product contained only preauthorized ingredients, the product could be marketed, possibly through self-certification. If the product used unapproved ingredients, the manufacturer would be required to submit a PMTA containing information on only those ingredients or meet established testing guidelines. The comments suggested that standards that could be used to assess the ingredients may include the U.S. Pharmacopeial Convention (USP), FDA's Generally Recognized as Safe (GRAS) standards, the New Drug Products Q3B(R2) guidance; and the Food Chemicals Codex or FDA Redbook of Foods.

(Response) FDA disagrees. Section 910 of the FD&C Act requires FDA to evaluate the new tobacco product as a whole to determine whether the authorization of marketing of the product is appropriate for the protection of the public health. In addition, we note that GRAS status for a food additive does not mean that the substance is GRAS when inhaled, since GRAS status does not take inhalation toxicity into account and applies only to intended uses that may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (section 201(s) of the FD&C Act.).

(Comment 47) A few comments expressed concern as to the contemplated compliance periods for HPHC testing (with a proposed compliance period of 3 years following the effective date of the final rule) and the contemplated 24-month compliance period for marketing applications, because applicants will need to submit HPHC data with their PMTAs. They requested that FDA delay its enforcement of PMTA and SE application requirements until it has established an HPHC list and validated methodology for individual products.

(Response) While applicants should submit certain information about HPHCs as part of their applications, the requirement to submit HPHC listings under section 904 of the FD&C Act (21 U.S.C. 387d) is separate and distinct from the premarket review requirements under section 910. HPHC information submitted under section 904 will assist FDA in assessing potential health risks and determining if future regulations to address a product's health risks are warranted. For PMTAs, FDA expects that applicants will report the levels of HPHCs as appropriate for each product, so the reported HPHCs will differ among different product categories. Elsewhere in this issue of the **Federal Register**, FDA has made available draft guidance, which when final will describe FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products, including information regarding HPHCs. The Agency recommends that manufacturers consult with CTP's OS about what is appropriate in the context of a specific application.

FDA recognizes, however, that it could be difficult for certain manufacturers of the newly deemed products (*e.g.*, small businesses) to comply with the section 904 HPHC requirements for all of their currently marketed products. For example, contract laboratories may not be prepared for the large volume of requests for the testing of quantities of the HPHCs for all brands and subbrands of tobacco products marketed prior to the effective date. Thus, we have established a compliance period of 3 years for submission of this data under section 904 for products on the market as of the effective date. In addition, in the context of all newly deemed products considered in total, many products may be grandfathered and will thus not be required to obtain premarket authorization through one of three pathways—SE, exemption from SE, or premarket tobacco product applications (sections 905 and 910 of the FD&C Act). Given that the number of newly deemed products in total seeking PMTA orders likely will be much smaller than the total number of such tobacco products on the market as of the effective date (given that many products will be grandfathered and that some products may exit without submission of an application), FDA expects that the HPHC information submitted as part of these PMTA applications can be obtained within the 2-year submission period for newly deemed tobacco products. (FDA notes that the proportion of products that may qualify as grandfathered is likely to vary for different product categories. For example, the ENDS product category, for which the market has changed dramatically since 2007, is likely to have a smaller proportion of grandfathered products than some other product categories.)

Moreover, elsewhere in this issue of the **Federal Register**, FDA has made available a final guidance to provide information on how to establish and reference a Tobacco Product Master File (TPMF). FDA notes that we expect reliance, to the extent applicable, on TPMFs to increase efficiency and reduce any burdens on manufacturers. As discussed in section IX, because of the nature of upstream supply of many components for ENDS products, especially e-liquids, FDA anticipates that commercial incentives will be sufficient to drive manufacturer reliance on the system of master files. We note that, at present, FDA understands, based on publically available information, that the number of entities engaged in upstream production of liquid nicotine and flavors specifically developed for use with e-liquids is in the range of seven to thirteen entities (see earlier discussion in response to comment 34). Given the nature of the marketplace, FDA expects that the master file system will be widely appealing and widely utilized by the ENDS industry.

(Comment 48) Several comments noted that large numbers of tobacco product manufacturers waited until March 22, 2011 (the date that provisional SE reports were due for the original tobacco products subject to the FD&C Act) to submit their SE reports. They considered this an abuse of the process and expressed concern that manufacturers of newly deemed products would act similarly, particularly with a 24-month compliance period. They suggested that FDA expressly require companies to meet all other requirements, including ingredient reporting and quality controls, to be able to avail themselves of this extended compliance period. Other comments stated that any compliance period should be contingent on FDA issuing orders on all pending SE reports already submitted to the Agency.

(Response) FDA understands concerns about the Agency's timely review of applications given the influx of SE reports that FDA received at the close of the SE provisional period (March 22, 2011). However, FDA has taken several steps to address the resulting backlog and to provide helpful feedback to industry to encourage more complete, streamlined submissions and reviews, including: (1) Encouraging teleconferences between the assigned regulatory health project manager and the applicant; (2) streamlining the SE report review process by modifying the preliminary review so that it focuses only on administrative issues and allowing submission deficiencies to be communicated to the applicant more quickly; (3) providing information on FDA's Web site about the three pathways available to market products (including SE) and developing public Webinars to explain the Agency's processes; and (4) publishing guidance documents. On March 24, 2014, FDA announced that the Agency no longer has a backlog of regular SE reports awaiting review. The Agency is now reviewing regular SE reports as they are received. FDA expects that these steps will help reduce the time it will take FDA to review submissions for newly deemed products. In addition, FDA has specified end dates for the compliance periods for such products, after which such products on the market without authorization (even if applications submitted during the relevant compliance periods are still under review) will be subject to enforcement. We note that these staggered compliance dates will help to manage the flow of applications into FDA. If an applicant wishes to discuss a product application, the applicant may request a meeting as set forth in FDA's final guidance entitled "Meetings with Industry and Investigators on the Research and Development of Tobacco Products" (announced May 25, 2012, 77 FR 31368).

(Comment 49) At least one comment suggested that FDA should require manufacturers that have not received their marketing authorizations within 1 year after the effective date of the final deeming to include a statement on their packaging and labeling indicating that the product is pending FDA evaluation under the Tobacco Control Act.

(Response) FDA declines to issue such a labeling requirement at this time. We do not have evidence that the statement will be appropriate for the protection of the public health, as determined with respect to the risks and benefits to the population as a whole (which is the standard for such a requirement under section 906(d) of the FD&C Act). FDA also is concerned about consumer confusion or misconceptions that could result from such a requirement.

(Comment 50) At least one comment suggested that application of premarket review requirements to the newly deemed products (namely, e-cigarettes) is unnecessary, because the benefits that would accrue as a result of deeming are independent of the premarket review provisions.

(Response) FDA disagrees. The premarket provisions of the statute apply automatically to deemed products. While FDA outlined in the NPRM a number of public health benefits that would accrue as a result of deeming products subject to chapter IX as a whole (79 FR 23142 at 23148 and 23149), as explained in this document, FDA believes that the public health benefits that will accrue from the premarket review provisions are substantial. Implementation of these provisions will allow FDA to monitor product development and to prevent potentially more harmful or addictive products from reaching the market. Premarket review is especially critical given the changing nature of the ENDS technology and industry and the increasing interest in these products from youth and young adults. FDA's premarket review also will increase product consistency. For example, FDA's oversight of the constituents of e-cigarette and other ENDS cartridges will help to ensure quality control relative to the chemicals and their quantities being aerosolized and inhaled. At present, there is significant variability in the concentration of chemicals among some products—including variability between labeled content and concentration and actual content and concentration (see section VIII.D). Without a regulatory framework, users will be subject to significant variability among products, raising potential public health and safety issues.

IV. Implementation

FDA's proposal stated that part 1100, deeming additional tobacco products to be subject to chapter IX of the FD&C Act, and the minimum age and identification and vending machine restrictions in part 1140 would be effective 30 days after publication of the final rule and listed compliance periods for different requirements. FDA received many comments regarding the proposed effective date, compliance periods, and other enforcement issues. A summary of these comments and FDA's responses are included as follows.

A. Effective Date for Rule

FDA proposed that part 1100, deeming products to be subject to the chapter IX automatic provisions, and the minimum age and identification and vending machine restrictions in part 1140 be effective 30 days from the publication date of the final rule. Based on our review of comments, FDA is finalizing this rule so that the automatic provisions, minimum age provisions, and vending machine restrictions will be effective 90 days from the date of the final rule's publication, as explained in this document. The compliance periods for other sections are discussed in this section.

(Comment 51) A few comments expressed concern regarding the effective date of the deeming provisions in part 1100, which is also the effective date of the minimum age and identification regulations. They stated that a 30-day effective date for the minimum age and identification regulations provides too small a window of time for retailers to adjust employee training curricula, train and educate employees, raise awareness of the new requirements, and adjust in-store or point-of-sale job aids to ensure compliance. These comments requested a 6-month compliance period for both the youth access and vending machine provisions.

(Response) FDA recognizes that certain retailers may need more than 30 days to begin compliance with the youth access and vending machine restrictions included in this rule. For example, ENDS retail establishments or cigar retailers that have not previously been subject to similar restrictions for cigarettes and smokeless tobacco may need additional time to implement these regulations. To address these situations, FDA is establishing a 90-day effective date for this deeming provision and the accompanying automatic provisions in the FD&C Act, as well as the minimum age and identification requirements and vending machine restrictions. FDA does not believe that a 6-month compliance period is necessary to educate retailers on these requirements given that many retailers also sell products that are currently subject to Federal and/or State and local regulations regarding minimum age and identification.

(Comment 52) Some comments suggested that FDA delay the effective dates of all deeming provisions until the Agency can issue product standards (under section 907) and good manufacturing practice regulations (under section 906(e)), as these are the most important requirements for the newly deemed products. They stated, however, that all rulemaking on e-cigarettes should be delayed until the science is firmly established to allow for more informed FDA decisionmaking.

(Response) FDA disagrees. As we have stated throughout the document, FDA has data regarding health harms generally associated with all of the categories of tobacco products regulated under this rule (including ENDS). FDA is regulating these products in accordance with this knowledge. We will continue to build upon our product-specific knowledge through the information we receive as a result of the application of the FD&C Act's automatic provisions, such as ingredient reporting and the reporting of HPHCs, to newly deemed tobacco products. In addition, as discussed in the NPRM, FDA believes that many public health benefits will accrue as a result of deeming these products (79 FR 23142 at 23148 and 23149). It would not protect the public health to forego implementation of these provisions until FDA can issue final product standards and tobacco product manufacturing practice regulations. It is also important to note that this final deeming rule is a foundational rule that enables FDA to issue future regulations if FDA determines that they would be appropriate for the protection of public health.

(Comment 53) Comments stated the NPRM is a "major rule" according to the

Office of Information and Regulatory Affairs, 5 U.S.C. 804(2) (1996), and the Congressional Review Act mandates that the rule cannot take effect until 60 days after the final rule is published in the **Federal Register** (5 U.S.C. 801(a)(3) (1996)). Therefore, they requested that FDA change the effective date for this rule and the compliance periods for parts 1100 and 1140 to at least 60 days following publication of the final rule.

(Response) FDA is providing a 90-day effective date for parts 1100 and 1140 with this final rule.

B. Compliance Periods for Certain Provisions

To avoid confusion about existing dates in the FD&C Act that are based on the date of enactment of the law and to provide time for firms to comply with provisions that require labeling changes or information submissions to the Agency, FDA proposed compliance timeframes for certain provisions. The final compliance dates are included in tables 2 and 3.

(Comment 54) Comments requested that FDA impose the same requirements on the newly deemed products that apply to currently regulated products, including the same compliance periods for all provisions and the same marketing and advertising restrictions. In addition, they stated that establishing exemptions would create a significant administrative burden for FDA, and that a single, comprehensive plan would be easier for industry to understand and for the Agency to implement.

(Response) With this final rule, FDA is deeming additional tobacco products subject to its chapter IX tobacco authorities. This means that newly deemed products will be subject to all provisions in the FD&C Act applicable to "tobacco products" in the same way that currently regulated tobacco products are also subject to those provisions. Under section 901, FDA is authorized to deem products subject to "chapter IX," not to particular provisions of chapter IX. Thus, there are no exemptions from particular requirements for any product category (although FDA is announcing enforcement policies for certain requirements and for small-scale tobacco product manufacturers as discussed throughout this document). FDA is subjecting covered tobacco products to the additional provisions (*i.e.*, age and identification requirements, vending machine restrictions, and health warning requirements) discussed in this final rule. If FDA later determines that further marketing and advertising restrictions for newly deemed products are appropriate and meet the applicable standard in section 906(d), FDA will follow the requirements of the APA to implement such restrictions.

With respect to compliance periods, FDA is providing different compliance periods for certain automatic requirements of the FD&C Act that are generally similar to the timeframes provided in the statute for currently regulated products to meet certain requirements after the law's date of enactment.

1. HPHC Reporting Requirements (Section 904)

As of the effective date of this rule, the ingredient listing and HPHC reporting requirements of section 904 will apply to the newly deemed products. To provide manufacturers sufficient time to comply with these requirements, FDA is providing compliance periods for these requirements as stated in table 3.

(Comment 55) Most comments agreed with the compliance timeframes included in table 1B of the NPRM, aside from the HPHC requirements under section 904(a)(3) (79 FR 23142 at 23172 through 23174). They argued that the compliance period for testing and listing of HPHCs was not sufficient for several reasons, including: The costs associated with compliance; the lack of clear product-specific guidance; and the lack of available independent laboratories to complete the testing for the many small businesses that would be affected by the requirements.

(Response) The compliance period for HPHC reporting under section 904(a)(3) is the effective date of this rule plus 3 years. FDA intends to issue guidance regarding HPHC reporting, and later a testing and reporting regulation as required by section 915, with enough time for manufacturers to report given this compliance period. Section 904(a)(3) requires the submission of a report listing all constituents, including smoke constituents, identified as harmful or potentially harmful (HPHC) by the Secretary. Section 915 requires the testing and reporting of the constituents, ingredients, and additives the Secretary determines should be tested to protect the public health. The section 915 testing and reporting requirements apply only after FDA issues a regulation implementing that section, which it has not yet done. Until these testing and reporting requirements have been established, newly deemed tobacco products (and currently regulated tobacco products) are not subject to the testing and reporting provisions found under section 915. As noted elsewhere in this document, FDA does not intend to enforce the reporting requirements under section 904(a)(3) for newly deemed products before the close of the 3-year compliance period, even if the HPHC guidance is issued well in advance of that time. In addition, at this time, FDA also does not intend to enforce this requirement in relation to manufacturers of components and parts used for incorporation into finished tobacco products. In this context, a finished tobacco product refers to a tobacco product, including all components and parts, sealed in final packaging intended for consumer use (*e.g.*, filters or filter tubes sold separately to consumers or as part of kits). FDA considers an e-liquid to be a finished tobacco product if sold separately and not as part of an ENDS.

The Agency is committed to helping industry better understand the tobacco product review process and the requirements of the law and will continue holding public Webinars and meetings with industry. FDA has also published guidance on meetings with industry; this has enabled FDA to have many productive meetings to address companies' specific questions on their development of tobacco products. In addition, FDA intends to issue guidance regarding HPHC reporting, and later a testing and reporting regulation as required by section 915, with enough time for manufacturers to report given the 3-year compliance period for HPHC reporting. As noted elsewhere in this document, FDA does not intend to enforce the reporting requirements under section 904(a)(3) for newly deemed products before the close of the 3-year compliance period, even if the HPHC guidance is issued well in advance of that time.

2. Registration and Listing (Section 905)

As of the effective date of this rule, those persons who own or operate domestic manufacturing establishments engaged in manufacturing newly deemed tobacco products (including those that engage in the blending of pipe tobacco and the mixing of e-liquids as discussed in section IX.C) will be required to register with FDA and submit product listings under section 905. This deeming rule will not require foreign manufacturing establishments to register their establishments or to list their tobacco products in order to sell them in the United States. However, foreign manufacturing establishments will be required to comply with the registration and listing requirements of section 905 of the FD&C Act after a registration and listing rule is final and effective. Because the compliance period for registration and listing depends on the date of publication of this final rule, FDA intends to revise the current guidance ("Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments"), which FDA expects to issue within six months following the effective date of the final deeming rule, to clarify the compliance periods for manufacturers of newly deemed tobacco products.

(Comment 56) Most of those comments regarding the registration and listing requirements stated that the contemplated compliance period was sufficient, because these requirements are not costly or time-consuming for manufacturers, provided FDA's electronic submission system is working effectively. A minority of comments asked for a longer compliance period that would be based on FDA published guidance for individual product categories that includes examples of completed registration and listing forms.

Most of the comments also stated that foreign and domestic companies should be required to comply with registration and listing requirements at the same time to ensure fair and equal treatment among each product category. They stated that this was especially important given that many of the novel products are manufactured outside the United States and that comprehensive registration requirements will promote equitable assessment and collection of user fees.

(Response) FDA agrees with comments stating that the contemplated compliance period for registration and listing is sufficient. To provide additional assistance to newly deemed product manufacturers, FDA intends to provide examples of completed registration and listing forms for each major category of newly deemed products at least 6 months before the end of the compliance period. In addition, in 2013, CTP adopted a new electronic system, FDA Unified Registration and Listing System (FURLS), with capacity to accept registration and listing submissions for all FDA-regulated products, which has and will continue to simplify the process of submitting registration and listing information, making it more efficient for industry and providing faster access to this information by both FDA and industry. Unlike the previous eSubmitter process, FURLS is an online application that allows users to access multiple databases simply by going to the FURLS Web site and viewing and updating their data at any time. Questions regarding registration and listing requirements can be directed to CTP's call center at 1–877–CTP–1373 and to CTP's Office of Small Business Assistance, which is part of OCE.

Further, section 905 of the FD&C Act requires FDA to issue a rule through the notice and comment rulemaking process in order to apply the registration and product listing requirements to foreign manufacturers—the requirements for domestic manufacturers are immediately implemented and do not require a regulation. (Section 905(h) of the FD&C Act.) FDA has announced its intent to issue a rule regarding registration and listing, including application of the requirements to foreign manufacturers, in the Unified Agenda (RIN No. 0910–AG89).

3. Modified Risk (Section 911)

As of the effective date of this rule, section 911 will automatically apply to the newly deemed products. Among other requirements, this section prohibits the introduction or delivery for introduction into interstate commerce of MRTPs, including those with certain specified descriptors ("light," "low," "mild," or similar descriptors) in the label, labeling, and advertising of such products, unless manufacturers submit a MRTP application and receive FDA authorization before marketing. The basic requirement for premarket review of MRTPs will apply immediately upon the effective date. To provide manufacturers sufficient time to comply with the prohibition on products with specified descriptors, FDA is providing a compliance period for this requirement, as stated in table 3.

(Comment 57) The comments generally stated the 1-year compliance period for section 911(b)(2)(A)(ii) was sufficient, but some stated that it was unnecessary for FDA to provide any compliance period and that manufacturers should begin complying with these provisions upon the final rule's effective date.

(Response) FDA believes that the 12-month period to comply with the restrictions set forth in section 911(b)(2)(A)(ii) (after which a manufacturer may not manufacture, without an order in the effect, any tobacco product which contains "light," "low," or "mild," or similar descriptors on label, labeling, or advertising), and the additional 30-day period where manufacturers may continue to distribute products into domestic commerce, are consistent with the effective dates originally included in the Tobacco Control Act. Under section 911(b)(3), the prohibition on the manufacture and distribution of tobacco products containing "light," "low," or "mild," or similar descriptors appearing on labeling, labels, or advertising (unless an order was issued authorizing their marketing) took effect 12 months after the date of enactment of the Tobacco Control Act, and manufacturers also had an additional 30 days after the effective date to continue to introduce these products with these descriptors into domestic commerce. Additionally, this compliance policy balances the need to help consumers better understand and appreciate the health risks of these newly deemed tobacco products while providing manufacturers with sufficient time to revise the label, labeling, and advertising as appropriate.

This compliance policy does not extend to other MRTPs as defined in the remaining sections of 911(b) (*e.g.,* tobacco products of which the label, labeling, or advertising explicitly or implicitly represents that the product presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products, the product or its smoke contains a reduced level/presents a reduced exposure to a substance, or the product or its smoke does not contain/is free of a substance; or action taken by a manufacturer directed to consumers through media or otherwise, other than through the product's label, labeling, or advertising that would be reasonably expected to result in consumers believing that the tobacco product or its smoke may present a lower risk of disease or is less harmful than one or more commercially marketed tobacco products, or presents a reduced level/exposure to substance(s), or does not contain/is free of a substance(s)). Just as these provisions took effect immediately upon the enactment of the Tobacco Control Act for currently regulated products, newly deemed products will be expected to comply with these provisions on the effective date of part 1100. The agency believes this is necessary in order to ensure that consumers better understand and appreciate the health risks of newly deemed products, particularly where a product's label, labeling, or advertising makes express or implied claims of reduced risk or less harm or that a product has reduced levels of or is free of a substance(s).

4. Required Warnings

(Comment 58) A few comments suggested that manufacturers should be required to implement the proposed health warnings within 6 months following the effective date of this rule. One comment stated that the health warnings should take effect no later than 12 months from publication of the final rule. They stated that the delay in implementing the health warnings has the potential to continue to foster the perception, particularly on the part of youth, that e-cigarettes are safe products and the misunderstanding that they have been found to be safe and effective cessation products. They also stated that the shorter compliance period is necessary to quickly make consumers aware of the possibility of becoming addicted to e-cigarettes.

(Response) FDA has considered the comments and the time and resources it will take for manufacturers to comply with the health warnings requirements and the need to provide these messages to consumers and has determined that the proposed effective date of 24 months after publication of this rule for the warning requirements in part 1143 is appropriate.

5. Compliance Period Tables

The final compliance period table for various provisions is included in this document. (The compliance policy for submission of premarketing applications is discussed in section V.A.) To clarify, effective dates differ from compliance periods. While a requirement is effective on a certain date (here, the "effective date"), for many provisions, FDA is providing a compliance period with additional time during which FDA does not intend to enforce compliance with the regulation. We note that the compliance periods and provisions for sections 904(a)(3) and 904(a)(4) have been consistent with FDA's approach for currently marketed tobacco products and FDA's final guidance entitled "Tobacco Health Document Submission" (75 FR 20606, April 20, 2010). In addition, FDA has revised the compliance period for section 903(a)(8) of the FD&C Act from "effective date of part 1100 PLUS 1 year" to "24 months after the publication of this final regulation" so that it is consistent with the effective dates for the health warning requirements in part 1143 of this final rule.

TABLE 2—COMPLIANCE WITH VARIOUS AUTOMATIC PROVISIONS

FD&C Act citation	Compliance period
902(1)–(5), (8)	Effective date of part 1100.
903(a)(1)	Effective date of part 1100.
903(a)(6)–(7)	Effective date of part 1100.
904(c)(2), (3)	Effective date of part 1100.
905(i)(3)	Effective date of part 1100.
911(a), 911(b) [with the exception of products sold or distributed using the descriptors set forth in 911(b)(2)(A)(ii)].	Effective date of part 1100.
919(a)	See FDA's final rule revising the current user fee regulations published concurrently with this final deeming rule.

TABLE 3—COMPLIANCE PERIODS FOR OTHER PROVISIONS

FD&C Act citation	Compliance period
903(a)(2)	24 months after the publication of this final regulation. * This is designed to match the 24 month effective date of the health warnings.
903(a)(3)	Effective date of part 1100 PLUS 1 year. * This is designed to match the 1 year deadline in the FD&C Act for currently regulated products.
903(a)(4)	24 months after the publication of this final regulation. * This is designed to match the 24 month effective date of the health warnings.
903(a)(8)	24 months after the publication of this final regulation. * This is designed to match the 24 month effective date of the health warnings.
904(a)(1), 904(c)(1)	Effective date of part 1100 PLUS 6 months (products on the market as of the effective date) or 90 days before delivery for introduction into interstate commerce (products entering the market after the effective date). * This matches the timeframes provided in this section.
904(a)(3)	Effective date of part 1100 PLUS 3 years or, for products delivered for introduction into interstate commerce later than 3 years after the effective date, 90 days before delivery for introduction into interstate commerce (products entering the market after the effective date). * This matches the timeframes provided in this section.
904(a)(4)	Effective date of part 1100 PLUS 6 months. * This matches the timeframes provided in this section.
905(b), (c), (d), (h)	If the final rule publishes in the second half of the calendar year, FDA intends to issue a compliance policy with a compliance period for registration that is no later than 6 months into the subsequent calendar year. * This matches the timeframes provided in this section.
905(i)(1)	Same compliance period as that for initial registration; see date specified for 905(b).
907(a)(1)(B)	Effective date of part 1100 PLUS 2 years. * This matches the timeframe provided in this section.
911(a), (b)(1), (b)(2)(A)(ii), (b)(3)	Use of "light," "low," and "mild" descriptors: Effective date of part 1100 PLUS 1 year (stop manufacture); Effective date of part 1100 PLUS 13 months (stop distribution). * This matches the timeframes provided in this section.
920(a)(1)	24 months after the publication of this final regulation. * This is designed to match the 24 month effective date of the health warnings.

6. Other Enforcement Issues

(Comment 59) A few comments expressed concern that this rule will result in the growth of an illicit market for certain newly deemed tobacco products, particularly e-cigarettes and e-liquids. They suggested that such an illicit market could make products more available and more attractive to youth and young adults. They also feared that this illicit market would worsen if FDA were to ban certain e-liquid flavorings, stating that the deeming rule (and/or a ban on certain flavorings) would result in consumers mixing their own e-liquids, even though the comments stated that most consumers are not adept at handling or mixing chemicals. These "do-it-yourself manufacturers," as the comments referred to them, would increase health risks, because more individuals possessing pure nicotine could lead to more accidental poisonings and the possibility of overdoses. Comments pointed to a survey from an e-cigarette forum which stated that "[a]bout 79 percent of respondents said they would 'look to the black market' if products they use 'were banned tomorrow,' while 14 percent said they would return to smoking analog cigarettes" (*e.g.*, Ref. 44).

Comments also expressed concern that regulation will increase prices of the newly deemed tobacco products and consumers will turn to an illicit market to obtain products for lower prices. For example, they stated that some markets for cigarettes (*e.g.*, New York) experience smuggling rates of beyond 50 percent, as consumers seek products for lower costs. These comments expected a similar result to occur after the deeming rule becomes effective (see Ref. 45).

Further, they stated that this illicit market would cause additional problems like stifling innovation for regulated companies, because companies operating in the illicit market would not be complying with costly regulations and would be able to take advantage of innovations elsewhere in the world. They theorized that this illicit market would favor very small domestic producers over existing medium-sized domestic manufacturers with better quality control and safety mechanisms.

In addition to concerns about e-cigarettes, comments expressed concerns about the potential for illicit markets for other newly deemed products. For example, they stated that a final deeming regulation (without an exemption for premium cigars) would exacerbate the black market that already exists for premium Cuban cigars. The comments also noted that those involved in the waterpipe tobacco industry already operate more informally (*e.g.*, without local regulation) and, therefore, the deeming regulation would cause more business to be transacted in illicit markets. They also expressed concern about the development of a flourishing illicit market if flavors were not permitted in the deemed products.

(Response) FDA understands these concerns, but believes that this rule will not increase current illicit practices or create new illicit markets, because FDA is not banning any tobacco product with this deeming rule. Even if some illicit trade were to develop in an attempt to evade the requirements of this rule, FDA does not believe it would result in a volume sufficient to outweigh the public health benefits of the rule. FDA authority over the newly deemed tobacco products will give it means to determine which products are legally on the market and which are counterfeit or otherwise illegally marketed. The Tobacco Control Act gives the Agency these and other authorities, such as section 920 of the FD&C Act (21 U.S.C. 387t), to help address illicit tobacco products.

In addition, FDA recently commissioned a report from the National Research Council and Institute of Medicine Panel to help us better understand and consider all aspects of illicit tobacco markets (Ref. 46). This report focused mainly on combustible products, especially cigarettes, as they are the subject of most illicit tobacco trade. The relevance of those findings to an assessment of the potential for illicit trade in tobacco products more generally in the United States, such as ENDS products, is open to question. Overall, illicit trade in cigarettes is under 10 percent. It is not clear if illicit trade in any of the newly deemed products will be greater or less than that observed for cigarettes. Evidence from Canada shows the development of an illicit market in ENDS products in that particular context where the government currently regulates all nicotine-containing electronic smoking products as medical devices under the Food and Drugs Act, regardless of the products' health claims.[12] Canada does, however, have a legal market for the sale of non-nicotine containing ENDS products. Despite the fact that Health Canada has not approved any nicotine-containing ENDS products for sale or importation in the country a 2015 e-cigarette usage study (Ref. 48) showed usage rates among Canadian populations that were similar to those among U.S. populations.

Despite the potential for some illicit ENDS market activity to occur, FDA emphasizes that the presence of an illicit market does not affect its legal authority to regulate such products and that there is evidence that many ENDS manufacturers will likely submit premarket applications in the United States.

Moreover, as stated previously, FDA expects that the public health benefits that likely will accrue as a result of this final rule will be greater than the negative effects that could result if there were an increase in illicit markets. This final deeming rule will afford FDA additional tools to reduce the number of illnesses and premature deaths associated with tobacco product use. For example, FDA will be able to obtain critical information regarding the health risks of newly deemed tobacco products, including information derived from ingredient listing submissions and reporting of HPHCs required under the FD&C Act. FDA will also receive information on the location and number of manufacturing establishments, which will allow the Agency to establish effective compliance programs. In addition, because of this rule, FDA will be able to take enforcement action against manufacturers of newly deemed products who make unsubstantiated MRTP claims or false or misleading claims about their products, thus allowing for better-informed consumers and helping to prevent the use of misleading campaigns targeted to youth populations. It will also prevent from entering the market new products that are not appropriate for the protection of public health, are not substantially equivalent to a valid predicate product, or are not exempt from SE. Finally, the newly deemed tobacco products may be subject to future regulations that FDA determines are appropriate.

FDA believes that this rule will not stifle innovation but could, instead, encourage it. The greater regulatory certainty created by the premarket review process may encourage companies to invest in creating potentially beneficial novel products, with greater confidence that improved products will not be competing against equally novel, but more dangerous, products. For example, a company may be more willing to invest the additional resources needed to ensure that its product is designed and manufactured with appropriate methods and controls.

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[12] ENDS and e-liquids that do not contain nicotine can be legally sold in Canada. Health Canada issued a Notice in 2009 regarding electronic cigarette products that contain nicotine (Ref. 47).

The PMTA pathway will incentivize development of tobacco products that pose less risk to human health by limiting market access by riskier competitor products. Furthermore, since the "appropriate for the protection of the public health" standard involves comparison to the general tobacco product market, FDA believes that, over time, the premarket authorities will move the market toward less risky tobacco products.

C. Policy for Certain Regulatory Requirements for All Manufacturers of Newly Deemed Products

FDA received many comments expressing concern regarding the regulatory and financial burdens associated with certain automatic provisions that will apply to newly deemed products once this rule becomes effective. In response to comments, FDA has considered instances in which the Agency has implemented compliance policies for currently regulated products. Accordingly, the Agency is announcing the following compliance policy with respect to newly deemed products. As with any such policy, the Agency will review and revise this policy as appropriate. If FDA were to change this policy, the Agency would provide notice to affected entities.

1. Substantial Equivalence

As provided in guidance for currently regulated products ("Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Edition 2)" (80 FR 53810, September 8, 2015)), FDA does not intend to enforce against manufacturers who make tobacco blending changes without a marketing authorization if the tobacco blending changes are intended to address the natural variation of tobacco (*e.g.,* due to variation in growing conditions) in order to maintain a consistent product. However, FDA does intend to enforce the premarket authorization requirements for tobacco blending changes that are intended to alter the chemical or perception properties of the new product (*e.g.,* nicotine level, pH, smoothness, harshness).

FDA does not intend to take enforcement action for at least 30 calendar days from the date the not substantially equivalent (NSE) order issues for those products that are in a retailer's current inventory at a specific retail location on the date FDA issues the NSE order. This policy extends only to tobacco products that are already in a retail store that offers the products for sale directly to adult consumers.

FDA has provided guidance ("Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Edition 2)") on currently regulated tobacco products stating that a change in supplier, where the new supplier is used for the same ingredient, additive, component, part, or material, with identical specifications, would not render a new tobacco product. This guidance also will apply to newly deemed products.

2. Reporting of HPHCs

FDA intends to issue guidance regarding HPHC reporting, and later a testing and reporting regulation as required by section 915, with enough time for manufacturers to report given the 3-year compliance period for HPHC reporting. Section 904 (a)(3) requires the submission of a report listing all constituents, including smoke constituents, identified as harmful or potentially harmful (HPHC) by the Secretary. Section 915 requires the testing and reporting of the constituents, ingredients, and additives the Secretary determines should be tested to protect the public health. The section 915 testing and reporting requirements apply only after FDA issues a regulation implementing that section, which it has not yet done. Until these testing and reporting requirements have been established, newly deemed tobacco products (and currently regulated tobacco products) are not subject to the testing and reporting provisions found under section 915. As noted elsewhere in this document, FDA does not intend to enforce the reporting requirements under section 904(a)(3) for newly deemed products before the close of the 3-year compliance period, even if the guidance is issued well in advance of that time. At this time, FDA also does not intend to enforce this requirement in relation to manufacturers of components and parts used for incorporation into finished tobacco products. In the future, we intend to evaluate if there are additional constituents that are present in newly deemed products and should be included in the HPHC list for reporting. FDA also intends to issue guidance to further refine the list of reportable HPHCs based on product class.

3. Tobacco Health Document Submission

Although section 904(a)(4) sets out an ongoing requirement to submit tobacco health documents developed after June 22, 2009 (the date of enactment of the Tobacco Control Act), FDA generally does not intend to enforce the requirement with respect to all such documents at this time, so long as a specified set of documents is submitted by the effective date plus 6 months. FDA intends to publish additional guidance that specifies the scope of such health documents within three to six months of the publication date of this final rule, with sufficient advance time for manufacturers and importers to prepare their submissions.

FDA does intend to collect other tobacco health documents developed after June 22, 2009, but before doing so the Agency will publish additional guidance specifying the timing of subsequent submissions. Note that, despite this compliance policy with respect to timeliness of submissions, manufacturers and importers are still to preserve all tobacco health documents developed after June 22, 2009, for future submissions to FDA. Failure to submit tobacco health documents developed after June 22, 2009, because of a failure to preserve them after publication of this rule will constitute a violation of section 904(a)(4).

4. Compliance Policy for Components and Parts

As discussed in section VI.B, at this time FDA does not intend to enforce certain requirements for components and parts of newly deemed products that are sold or distributed for further manufacturing into finished tobacco products.

D. Compliance Policy Regarding Certain Provisions and Small-Scale Tobacco Product Manufacturers

In the NPRM, FDA requested comment on the ability of smaller manufacturers of newly deemed tobacco products to fully comply with the requirements of the FD&C Act and how FDA might be able to address those concerns. Considering the comments and FDA's finite enforcement resources, the Agency's view is that those resources may not be best used in immediately enforcing the provisions of this rule against certain manufacturers that are small-scale tobacco product manufacturers and that fail to comply with certain requirements of the FD&C Act. Therefore, FDA generally intends to grant small-scale tobacco manufacturers additional time to respond to SE deficiency letters and to not bring enforcement action against those small-scale tobacco product manufacturers who submit ingredient listings within 12 months of the effective date of this rule, and is granting small-scale tobacco product manufacturers an additional six-month compliance period for the tobacco health document submission requirements. As with any such policy, FDA will review and revise these policies as appropriate. If FDA were to change these policies, FDA would do so consistent with its Good Guidance Practices regulations.

For purposes of this compliance policy, FDA generally considers a "small-scale tobacco product manufacturer" to be a manufacturer of any regulated tobacco product that employs 150 or fewer full-time equivalent employees and has annual total revenues of $5,000,000 or less. FDA considers a manufacturer to include each entity that it controls, is controlled by, or is under common control with. To help make FDA's individual enforcement decisions more efficient, a manufacturer may voluntarily submit information regarding all relevant factors, including information regarding employment and revenues. Interested manufacturers may contact CTP's call center at 1–877–CTP–1373 for questions regarding this compliance policy. We note that FDA's thinking regarding "small-scale tobacco product manufacturer" differs from the definition of "small tobacco product manufacturer" in section 900(16) of the FD&C Act.

FDA notes that our thinking regarding what a "small-scale tobacco product manufacturer" is for purposes of this policy is designed to align with the nature of the specific relief provided. That is, the relief provided (as described throughout this document) relates generally to requirements for entities to compile or report information. These activities may require an investment of employee time and/or financial resources that is more challenging for the smallest entities to achieve. For these reasons, the threshold takes note of both employee resources (FTEs) and financial resources (annual revenues), ensuring that those entities with the most limited human and financial resources are uniquely considered in FDA's decisions about enforcement of these provisions, precisely because the provisions may require resources not as readily available to these entities. Further, as stated elsewhere in this document, in formulating its thinking, FDA has considered all available data on employment, revenues, production volume and other details of operation for current manufacturers of newly deemed products. In addition, FDA notes that its current approach reflects a careful review of the potentially unique interests of the smallest tobacco product manufacturers as considered in light of the Agency's statutory obligations regarding the protection of public health.

1. SE Extension Requests (Section 905(j))

Although information adequate to make submissions should be available to all manufacturers, we expect small manufacturers to have more difficulty in putting this information together in an SE Report. FDA presently intends, for the first 30 months following the effective date of this rule, to grant extensions to small-scale tobacco product manufacturers for SE reports that need additional time to respond to SE deficiency letters. Extensions are not automatically granted. Requests will be considered on a case-by-case basis. Any extensions granted are likely to be limited in time—for example, where a manufacturer normally might have 90 days to respond to a deficiency letter, FDA will, for small-scale tobacco product manufacturers, grant an additional 30 days for such a response. FDA encourages all small-scale tobacco product manufacturers, especially those with limited or no experience with the SE pathway, to submit SE reports as early as possible. FDA is not instituting a similar policy for extension requests related to PMTAs (nor is it providing additional time for small-scale tobacco product manufacturers to prepare PMTAs) given the already-extended compliance period for PMTAs, which provides an additional 6 months to submit a PMTA, discussed in section V.A.

2. Tobacco Health Document Submissions (Section 904(a)(4))

To address concerns of small-scale tobacco product manufacturers regarding the submission of certain health documents, and in recognition of FDA's current enforcement priorities, FDA, for an additional 6 months following the end of the generally applicable compliance period, intends not to bring enforcement action against those small-scale tobacco product manufacturers who submit the required information.

3. Ingredient Listing Submissions (Section 904(a)(1))

FDA understands concerns that small-scale tobacco product manufacturers may need additional time to comply with section 904(a)(1)'s requirement that manufacturers submit ingredient lists. FDA presently intends not to bring enforcement action against those small-scale tobacco product manufacturers who submit section 904(a)(1)'s required information within 12 months of the effective date of this final rule.

4. Assistance With Marketing Applications

As with manufacturers in general, these small-scale tobacco manufacturers will also benefit from additional assistance with their marketing applications, including the designation of a Regulatory Health Project Manager so that they have a single point of contact in CTP's OS for questions about their marketing applications. They will also have access to an appeals process in the event that FDA denies their marketing applications (of which one small business has already taken advantage). Staff from CTP's OCE also will assist small-scale tobacco product manufacturers with identifying the types of documents that may be used to establish that their predicate products were on the market on February 15, 2007. This may include several calls or correspondence with the manufacturer as it submits different documents to the Agency.

5. Assistance in Navigating Other Regulatory Requirements

CTP's OCE will continue to assist small-scale tobacco product manufacturers in submitting rotational warning plans for FDA approval. These plans provide the firm's plan for how the required warnings will be displayed on the packaging and advertising for their product, as required by 21 CFR 1143.5. This may include several calls or correspondence with the small business as it seeks approval from the Agency.

CTP also has a system to assist small businesses in navigating the regulatory requirements of FDA. For example, the Center has a Call Center that triages all calls received from regulated industry. The Center's Office of Small Business responds to hundreds of calls, emails and correspondences from small businesses every year to assist them in answering their specific questions on how to comply with the law.

V. Premarket Review Requirements and Compliance Policy

Section 910 of the FD&C Act requires FDA authorization in order to market a new tobacco product. As described elsewhere, the FD&C Act contains three pathways for obtaining premarket authorization: SE exemptions, SE reports, and PMTAs.

Tobacco products that were on the market on February 15, 2007, are grandfathered and do not require premarket authorization. However, as described throughout this preamble, these products are subject to the other requirements of the statute.

A. Compliance Policy for Premarket Review Requirements

In the NPRM, FDA contemplated a compliance period of 24 months following the effective date for submitting a premarket application (SE exemption request, SE report, or PMTA), with a continued compliance period pending review of those applications (79 FR 23142 at 23144). In essence, the products would remain on the market during this indefinite compliance period until the agency rendered a decision on an application or the application was withdrawn.

Agency compliance/enforcement policies are not subject to the requirements that govern notice-and-comment rulemaking. *Prof'ls & Patients for Customized Care* v. *Shalala*, 56 F.3d 592 (5th Cir. 1995) (a compliance policy guide is not a substantive rule and not subject to APA's notice-and-comment rulemaking); *Takhar* v. *Kessler*, 76 F.3d 995, 1002 (9th Cir. 1996) (FDA compliance policy guides were not required to go through notice-and-comment procedures). But because the relevant time periods are of obvious interest, FDA laid out its anticipated compliance policy in the NPRM, and for similar reasons, is announcing its revised compliance policy here in the preamble to the final rule, rather than in a separate guidance document.

FDA has considered the comments and data submitted in response to the compliance policy in the NPRM. Some comments expressed concern about the extended availability of newly deemed, new tobacco products without scientific review. Others provided additional data regarding youth and young adult use of flavored tobacco products. In addition, others comments discussed the potential public health benefits from the availability of certain flavored newly deemed products (as discussed in section VIII.F). Taking the diverse comments on these issues, as well as the uncertainty regarding the positive or negative impact on public health from products like ENDS, into account, FDA has decided to implement the compliance policy with staggered initial compliance periods based on the expected complexity of the applications, followed by continued compliance periods for FDA review, such that our enforcement discretion will end twelve months after each initial compliance period. Under the policy described here for the staggered compliance periods, and while FDA is conducting its review of marketing applications during the continued compliance period, the Agency does not intend to take enforcement action against products remaining on the market for failure to have a premarket authorization order.

The compliance periods are staggered to improve efficiency for both FDA and regulated entities given that the time it takes to prepare premarket applications is dependent upon the type of application and complexity of the product. FDA intends to act as expeditiously as possible with respect to all new applications, while ensuring that statutory standards are met. Further, if at the time of the conclusion of the continued compliance period, the applicant has provided the needed information and review of a pending marketing application has made substantial progress toward completion, FDA may consider, on a case-by-case basis, whether to defer enforcement of the premarket authorization requirements for a reasonable time period.

FDA's revised compliance policy for premarket review aims to balance the public health concerns raised in the comments, allow the Agency to more efficiently manage the flow of incoming applications, and encourage high-quality premarket submissions from applicants.

In accordance with the Tobacco Control Act (sections 905 and 910 of the FD&C Act), a new tobacco product may be legally marketed only if FDA has authorized its marketing under one of the three premarket pathways described throughout this document. As a result of the compliance policy being announced, we expect that manufacturers of certain newly deemed, new tobacco products will continue to market their products without FDA authorization for certain time periods.

1. FDA's Revised Compliance Policy Is Informed by Comments Submitted in Response to the NPRM

FDA received many comments responding to its detailed requests for comment on possible compliance approaches. 79 FR at 23175–77. Some comments expressed concern that the compliance policy for premarket review described in the NPRM would permit the continued marketing of tobacco products that have not been reviewed under the public health standards of the Tobacco Control Act. For example, comments jointly submitted by 24 health and medical organizations stated that the contemplated 24-month compliance period and indefinite period of continued marketing during FDA's review included in the NPRM would prolong the public's exposure to products that contain nicotine, a highly addictive substance, and that do not meet the statutory standard for the grant of a marketing order (Comment No. FDA–2014–N–0189–79772.).

They also stated that this approach would allow manufacturers to continue to market the newly deemed products in ways that appeal to youth and to manipulate the content of these products in uncontrolled ways for an indefinite period (id.). They urged FDA to forego its contemplated compliance policy unless proper precautions are taken to limit the time period these products are allowed to remain on the market pending FDA review and authorization. In addition, they expressed concern that manufacturers, knowing that submission of an application will permit them to market products for years, have incentive to submit numerous applications (regardless of how incomplete or deficient the applications).

A network of tobacco control policy and legal specialists also expressed concern regarding the effect of continued marketing of new tobacco products that have not been reviewed under the applicable public health standards of the Tobacco Control Act (Comment No. FDA–2014–N–0189–81044). This organization noted the thousands of provisional SE reports submitted in the last five days before the statutory deadline, where such applications pending FDA review are "being used as placeholders that will allow the tobacco industry to continue to introduce new products at will, rather than following the proper legal procedures established by the Tobacco Control Act." They proposed a staggered timeline to submit applications under the three marketing pathways and a definite time period in which FDA would no longer exercise enforcement discretion with respect to premarket review of these products, noting that such an approach would incentivize industry to generate high-quality, complete applications within the initial compliance period.

In addition, two large organizations dedicated to the health of youth and young adults urged FDA not to implement a compliance period of any length for products sold in characterizing flavors other than tobacco or any covered tobacco products that use marketing practices known to appeal to children and youth (Comment No. FDA–2014–N–0189–67268; Comment No. FDA–2014–N–0189–79413.). Ranking minority members of the Energy and Commerce Committee, Health Subcommittee, and Oversight and Investigations Subcommittee, U.S. House of Representatives also called for a more protective compliance period than the one contemplated in the

NPRM, arguing that the proposed compliance period "puts the nation's youth at risk" (Comment No. FDA–2014–N–0189–80119). These comments, among others, all stressed the attractiveness of these newly deemed tobacco products to youth and young adults and the need for a more restrictive compliance policy to ensure that FDA limits the continued marketing of new tobacco products that have not been reviewed under the public health standards of the Tobacco Control Act.

Further, in response to FDA's requests for comments and data in the NPRM, numerous comments included data, research, and personal stories regarding the impact of candy and fruit flavors in tobacco products, including their appeal to youth and young adults, youth perceptions of flavored tobacco products, and their potential effect on transition from combusted tobacco product use (particularly, comments noted, in the case of adults using flavored ENDS to attempt to switch completely away from cigarette smoking). In addition, many comments urged FDA to take immediate action regarding flavored tobacco products as a result of increasing prevalence of flavored product use, and new data show continued growth in youth and young adult usage of flavored tobacco products.

In deciding upon a compliance policy to announce with this final rule, FDA considered all these comments and sought to balance the Agency's concern about the continued marketing of new tobacco products that have not been reviewed by FDA, the potential harmful impact of flavored tobacco products on youth, and the possibility that some of those products are playing a role in helping some tobacco users transition away from what is likely the most harmful form of nicotine delivery for an individual user, combusted tobacco products. FDA considered adopting the compliance policy as described in the preamble to the NPRM or a compliance policy that would provide different compliance periods for flavored and non-flavored tobacco products. FDA also considered providing different compliance periods for different product categories. For example, certain industry comments urged FDA to stagger compliance dates for different product categories, to delay compliance until FDA publishes a final guidance for each product category and to provide ENDS manufacturers a lengthier compliance period based on where they purport to fit within the risk continuum for nicotine-delivering products (*e.g.*, Comment No. FDA–2014–N–0189–81859; Comment No. FDA–2014–N–0189–10852).

In response to these comments, we note that nicotine use in any form is of particular concern for youth and pregnant women. On the other hand, some evidence suggests that ENDS may potentially promote transition away from combusted tobacco use among some current users and it is possible that there could be a public health benefit. See also section III.F for additional discussion of premarket pathways and the continuum of nicotine-delivering products. Based on currently available scientific evidence, this revised compliance policy strikes an appropriate balance among various, often competing, considerations.

2. FDA Is Announcing a Revised Staggered Compliance Policy With Staggered Timeframes and Continued Compliance Periods

In the interest of public health and taking into account the fact that there are products already on the market that will now be subject to premarket review, and in light of the considerations discussed in section 1 above, we have established the following compliance policy for newly deemed tobacco products. For those newly deemed products that were on the market on the effective date of this final rule, but that were not on the market on February 15, 2007, FDA is providing two compliance periods: One for submission and FDA receipt of applications and one for obtaining premarket authorization. Although such products are subject to the premarket review requirements of the FD&C Act, FDA does not intend to initiate enforcement action for failure to have premarket authorization during the respective compliance periods.

The compliance period for submission and FDA receipt of applications for newly deemed tobacco products under the three premarket pathways is as follows:

SE Exemption Requests—12 months from the effective date of this final rule

SE Reports—18 months from the effective date of this final rule

PMTAs—24 months from the effective date of this final rule

FDA is adopting the staggered timelines in this policy to account for the possibility that applicants may need additional time to gather information for certain premarket submissions that may require additional data. For example, if a manufacturer plans to submit an SE Exemption Request, the firm may only need to identify the product, provide certification statements, and gather scientific information on the additive change itself and any supporting information demonstrating that the change to the product is minor and an SE Report is not necessary. This is less information than that likely required for a PMTA. We expect this policy will also create a more manageable flow of premarket applications for newly deemed products. FDA expects that this staggering of deadlines also will benefit regulated industry, since it will allow for greater efficiency of FDA review and incentivize higher quality applications, which will reduce review times for all products. New products for which no application has been submitted by 24 months from the effective date of this rule will no longer be subject to this compliance policy and will be subject to enforcement.

Unless FDA has issued an order denying or refusing to accept the submission, products for which timely premarket submissions have been submitted will be subject to a continued compliance period for 12 months after the initial compliance period described previously. For such products, FDA does not intend to initiate enforcement for failure to have premarket authorization during this continued compliance period, which is as follows:

SE Exemption Requests—24 months from the effective date of this final rule (12 months after the compliance period for submission of such requests)

SE Reports—30 months from the effective date of this final rule (12 months after the compliance period for submission of such reports)

PMTAs—36 months from the effective date of this final rule (12 months after the compliance period for submission of such requests).[13]

Once the continued compliance period ends, new tobacco products on the market without authorization will be subject to enforcement. FDA will act as expeditiously as possible with respect to all new applications, while ensuring that statutory standards are met. FDA expects that this revised compliance policy will encourage the submission of high quality applications. By providing a date in which the continued compliance period ends, manufacturers will have an incentive to submit a complete application and respond substantively and expeditiously to questions raised during the review process instead of an incomplete or deficient application just to stay on the market indefinitely. This staggered compliance policy also will provide FDA with a more manageable flow of incoming applications to be reviewed, allowing the agency to more quickly make decisions on applications.

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[13] In addition, we note that any new tobacco product that was not on the market on the effective date of the rule (*i.e.*, 90 days after the publication date) is not covered by this compliance policy and will be subject to enforcement if marketed without authorization after the effective date.

FDA believes the staggered compliance periods will be sufficient for manufacturers to provide high quality applications. To help provide clarity regarding submission requirements for marketing applications, FDA has issued several guidance documents, and is finalizing other guidance documents, regarding the evidence needed for SE reports, including FDA draft guidance entitled "Substantial Equivalence Reports: Manufacturer Requests for Extensions or to Change the Predicate Tobacco Product" (79 FR 41292, July 15, 2014), and FDA guidance entitled "Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007," among others. FDA also has issued a draft guidance entitled "Applications for Premarket Review of New Tobacco Products" (76 FR 60055, September 28, 2011). In addition, elsewhere in this issue of the **Federal Register**, FDA has made available draft guidance, which when final will describe FDA's current thinking on some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products. If FDA determines that additional guidance is necessary to help manufacturers prepare marketing applications, FDA will issue additional guidance and publish a notice of availability in the **Federal Register**.

Further, if at the time of the conclusion of the continued compliance period, the applicant has provided the needed information and review of a pending marketing application has made substantial progress toward completion, FDA may consider, on a case-by-case basis, whether to defer enforcement of the premarket authorization requirements for a reasonable time period.

B. Responses to Comments Regarding Compliance Periods for Premarket Review Requirements

(Comment 60) FDA received many comments suggesting that we change the proposed compliance period for submitting marketing applications. Some comments suggested that the compliance period should be 24 months from the date FDA either announces its intent to no longer exercise enforcement discretion regarding premarket requirements or issues product-specific guidance on the preparation of PMTAs and the submission of HPHC testing results. They suggested that the issuance of the guidance documents be based upon the continuum of risk presented by nicotine-delivering products. Other comments suggested that we extend the PMTA compliance period to 5 years following the effective date of the final rule to give manufacturers sufficient time to complete the required testing.

(Response) FDA has already published for public comment draft guidance for industry regarding the submission of PMTAs, which when final will represent FDA's current thinking on this topic. In addition, elsewhere in this issue of the **Federal Register**, FDA has made available draft guidance, which when final will describe FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products. FDA is committed to helping industry better understand the tobacco product premarket review process and will continue to hold public Webinars and meetings with industry. FDA has also published guidance on meetings with industry, and FDA has had many productive meetings to address companies' specific questions on the development of tobacco products. As FDA reviews product applications for currently regulated and newly deemed categories of products, we intend to identify topics for which rulemaking or more product specific guidance is appropriate.

Moreover, along with finalizing this rule, FDA is setting forth an initial 2-year compliance period for the submission of a PMTA for newly deemed, new tobacco products, followed by a continued compliance period of up to 12 months for FDA to review the application. FDA believes that this will give sufficient time for manufacturers of such products to prepare high quality applications, and for FDA to review new applications as expeditiously as possible, while ensuring that the statutory standards are met. FDA's compliance policy is further described in section V.A of.

(Comment 61) Comments were split as to whether the NPRM's contemplated premarket review compliance timeframes (*i.e.,* 24 months for manufacturers to submit and for FDA to receive a marketing application) should apply to manufacturers of newly deemed products. While many industry comments sought additional time to comply with these requirements, many other comments suggested that the reason Congress delayed application of certain requirements to the currently regulated products (*e.g.,* cigarettes and smokeless tobacco) was to account for the creation, staffing, and training for a new FDA center. In addition, they stated that manufacturers of the newly deemed products cannot argue that they did not have adequate notice that they would need to comply with premarket requirements given that the Unified Agenda entry for the deeming proposal published on July 7, 2011, and was continually updated in subsequent Unified Agenda entries. They argued that establishing similar timeframes for the newly deemed products only benefits industry and is detrimental to the public health.

(Response) FDA has considered these comments and concludes that the staggered compliance periods included with this final rule are sufficient to allow manufacturers of previously unregulated tobacco products to submit applications without unduly delaying compliance. As stated elsewhere in this document, FDA has taken several steps to provide helpful feedback to industry to encourage more complete, streamlined submissions and reviews, including: (1) Encouraging teleconferences between the assigned regulatory health project manager and the applicant; (2) streamlining the SE report review process by modifying the preliminary review so that it focuses only on administrative issues and allowing submission deficiencies to be communicated to the applicant more quickly; (3) providing information on FDA's Web site about the three pathways available to market products (including SE) and developing public Webinars to explain the Agency's processes; and (4) publishing guidance documents. FDA intends to act as expeditiously as possible with respect to all new applications, ensuring that statutory standards are met.

(Comment 62) One comment suggested FDA allow for submission of a confidential e-cigarette product report in order to satisfy premarket review requirements. Similarly, another comment encouraged FDA to establish a "Tobacco Product Master File" (TPMF) system similar to the Agency's Drug Master File (DMF) and Food Additive Master File (FAMF) systems to allow for e-cigarette/personal vaporizer and e-liquid suppliers to submit confidential product information (including information on formulations, facilities, processes, and articles used in the manufacturing, processing, packaging, and storing of ingredients used).

(Response) FDA does allow for the submission and use of information to be incorporated by reference similar to master file programs for other FDA-regulated products. In addition, elsewhere in this issue of the **Federal Register**, FDA has made available a final guidance to provide information on how to establish and reference a TPMF. TPMFs are expected to help applicants of newly deemed products prepare premarket and other regulatory submissions because they can reference information in TPMFs rather than develop the information on their own.

Such a system would be especially helpful in the area of newly deemed tobacco products. Because of the nature of upstream supply of many components for ENDS products, especially e-liquids, FDA anticipates that commercial incentives will be sufficient to drive manufacturer reliance on the system of master files. We note that, at present, FDA understands that, based on publically available information, the number of entities engaged in upstream production of liquid nicotine and flavors specifically developed for use with e-liquids is small, in the range of seven to thirteen entities (see earlier discussion in response to comment 34). Given the nature of the marketplace, FDA expects that the master file system will be widely appealing and widely utilized by the ENDS industry.

(Comment 63) At least one comment stated that FDA should prioritize review of applications for products currently on the market over those seeking to enter the market and that FDA should establish clear review deadlines. Another comment suggested that priority should be given to those products whose marketing is unlikely to be seen by youth or is limited to existing adult users of the product.

(Response) During the initial implementation of the Tobacco Control Act, FDA received a large number of applications for currently marketed tobacco products. For these provisional products being reviewed through the SE pathway, in order to appropriately prioritize review, FDA performed a public health impact evaluation of the product's potential to raise different questions of public health. Currently marketed products with the highest potential to raise different questions of public health were placed in the tier to be reviewed first. If appropriate, FDA may consider using a prioritization method for newly deemed products.

FDA understands the value of establishing timelines for review of applications. For products not on the market on the effective date, FDA intends to establish review performance goals in the future as it did with currently regulated products.

(Comment 64) Some comments suggested that FDA continue to employ measures to ensure that completed SE reports and PMTAs are submitted as expeditiously as possible during the compliance period. They noted that FDA currently employs a "refuse-to-accept" policy for SE applications that allows FDA to make a threshold determination as to whether an SE application is sufficiently complete for the Agency to review. They stated that this policy will help to ensure that manufacturers of the newly deemed products do not try to unduly extend the time that products are marketed without FDA review of their applications.

(Response) FDA agrees. FDA plans to take all reasonable measures to ensure that applications are reviewed in a timely manner. FDA intends to continue employing its "refuse-to-accept" policy for SE Reports and other marketing applications (including SE Exemption Requests and PMTAs).

(Comment 65) Many comments suggested that FDA should develop a product category specific framework for submission of PMTAs in light of the large number of products for which PMTAs will be required, the size and cost of PMTAs, and FDA's available resources. The comments suggested that the compliance period should be based on the date FDA issues a category specific guidance document. The comments stated that, without category specific guidance, the PMTA process will effectively eliminate certain tobacco product categories, including the premium cigar industry. These comments asserted that it was Congress' intent to treat categories of tobacco products differently, as shown by the provisions banning flavored cigarettes, providing special considerations regarding menthol, establishing MRTP provisions, and creating baseline standards under sections 910 and 907.

(Response) As stated previously, the statute specifies the premarket pathways for tobacco products. Congress subjected all new tobacco products to the same premarket review requirements in sections 905 and 910. FDA has taken many steps to reduce and prevent backlogs of marketing applications pending FDA review and intends to act as expeditiously as possible with respect to all new applications, while ensuring that statutory standards are met. Elsewhere in this issue of the **Federal Register**, FDA has made available draft guidance, which when final will describe FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products. FDA may issue additional category specific guidance as appropriate. FDA is committed to helping industry better understand the tobacco product premarket review process and will continue to hold public Webinars and meetings with industry. In the category of cigars, and for premium cigars in particular, we expect that some products will remain on the market due to their status as grandfathered products, and that others will be able to make use of the SE pathway.

(Comment 66) While many comments stated that they needed additional time to comply with premarketing requirements, many other comments stated that the contemplated 2-year compliance period was too long. For example, comments jointly submitted by 24 health and medical organizations stating that the contemplated 24-month compliance period included in the NPRM would prolong the public's exposure to products that contain nicotine, a highly addictive substance, and that, in their view, do not meet the statutory standard for the grant of a marketing order (Comment No. FDA–2014–N–0189–79772.). They stated that it would allow manufacturers to continue to market the newly deemed products in ways that appeal to youth and to manipulate the content of these products in uncontrolled ways for an indefinite period (id.). These comments also argued that a 2-year compliance period will result in large numbers of adolescents experimenting with newly deemed products and becoming established e-cigarette users or users of other tobacco products. Some suggested that FDA reduce the compliance period to 6 months or 12 months and others suggested different compliance periods for SE reports, SE exemption requests, and PMTAs. One comment stated that FDA's burden estimates show that the PMTA process should take 18 months, so the compliance period should not extend beyond 18 months. Alternatively, other comments stated that there should not be any compliance period for products because the PMTA process was created to provide a higher scrutiny of review for new products with unknown health risks and a compliance period is contrary to this purpose. They also stated that a compliance period would allow the industry to flood the market place with products and manufacturers would not have an incentive to quickly develop high-quality applications. In addition, some comments suggested that FDA should not provide a compliance period for combusted products, such as pipe tobacco or cigars, because there is no parallel provision in the current statute for such products.

Some comments also suggested that manufacturers that sell flavored tobacco products or that market tobacco products to children should not be afforded any compliance period to satisfy the premarket review requirements of the FD&C Act (79 FR at 23176). For example, two large organizations dedicated to the health of youth and young adults urged FDA not to grant a compliance period of any length for products sold in characterizing flavors other than tobacco or any covered tobacco products that use marketing practices known to appeal to children and youth (Comment No. FDA–2014–N–0189–67268; Comment No. FDA–2014–N–0189–79413.).

Many comments also stated that manufacturers should not be able to avail themselves of the compliance period unless they agree to restrict their marketing to adults. However, some comments expressed concern as to how such a restriction could be administered in accordance with the First Amendment. In addition, Ranking minority members of the Energy and Commerce Committee, Health Subcommittee, and Oversight and Investigations Subcommittee, U.S. House of Representatives called for a more protective compliance period than the one contemplated in the NPRM, arguing that a 24-month compliance period "puts the nation's youth at risk" (Comment No. FDA–2014–N–0189–80119).

(Response) Once this rule takes effect, it will be illegal to sell these tobacco products to anyone under the age of 18. This final deeming rule is foundational, affording FDA with the authority to issue other regulations restricting sales and distribution, including advertising and promotion, under section 906(d).

FDA struck a balance by revising the initial compliance period for SE exemption requests and SE reports to 12 and 18 months, respectively, and is setting forth a 2-year compliance period for manufacturers of newly deemed, new tobacco products to submit (and FDA to receive) a PMTA. FDA believes that these time periods are sufficient for manufacturers to prepare high quality applications addressing the requirements in the statute.

FDA has given extensive consideration to having different compliance periods for flavored and non-flavored products. There is some evidence suggesting that flavored products pose a greater public-health risk than non-flavored products. FDA understands that the appeal of flavors and use of flavored tobacco products have an important role in the initiation and continued use of tobacco products, and in the health risks associated with use of these products. Many comments and studies provided data and information regarding youth and young adult use of flavored tobacco products in recent years. (*E.g.,* Refs. 49, 50, 51, 52, 53, 54, 55, 56). And flavors appear to encourage greater use. (*E.g.,* Ref. 57; Refs. 58, 59). The availability of appealing flavors is a commonly cited reason for use of non-combusted products among young tobacco users. (*E.g.,* Refs. 60, 61)

However, several considerations weigh against a shorter compliance period for flavored products. There are potential countervailing health concerns. At least some flavored combusted products (which are of particular concern because they are known to present similar risks to cigarettes and are youth appealing) are likely to be "grandfathered" and, therefore, would remain on the market regardless of the compliance period or enforcement policy for newly deemed, noncombusted flavored products. And, in any event, comments suggested that the availability of flavors in non-combusted tobacco products, such as ENDS, are appealing to current smokers of combusted products and may entice smokers to consider switching to e-cigarettes. (*e.g.,* Comment No. FDA–2014–N–0189–75088; Comment No. FDA–2014–N–0189–79096). And FDA is aware of emerging self-reports from current and former cigarette smokers supporting this claim. (*See* Refs. 62, 63.) Section VIII.F below discusses the preliminary evidence available to date regarding effectiveness of ENDS to help smokers transition from, or reduce their consumption of, combusted tobacco products. But at least some think that flavor variety is very important. (*See, e.g.,* Ref. 63). More research, especially longitudinal research, is needed to understand how flavoring impacts tobacco use over time (Ref. 64).

Finally, as with other tobacco products that will be regulated under this rule, FDA is cognizant of the transition that will be required for regulated entities. Several comments expressed concern that even the proposed 24-month compliance period was not sufficient to submit complete applications for all of their products. For example, one comment noted that most of the e-cigarette market "are small and medium-sized businesses owned and operated by individuals and families [and] most, if not all of these smaller enterprises lack the resources to tackle such a high administrative burden" associated with submitting multiple PMTAs within the time period (Comment No. FDA–2014–N–0189–80496). Several comments also expressed concern that the 24-month proposed compliance period would benefit larger companies with more resources to complete product applications at the expense of small and mid-size companies (*e.g.,* Comment No. FDA–2014–N–0189–76162). FDA notes that a shorter period would have an even greater impact on these businesses.

In light of these considerations, FDA believes that a two-year compliance period for flavored products, as with other tobacco products, represents the exercise of its enforcement discretion in a way that strikes an appropriate balance between providing industry time to transition and protecting the public health. Over time, FDA expects to see additional data on the role of certain flavored products in supporting reduction in or abstinence from the use of combusted products, as well as further data on the role of flavored products in youth initiation, use, and dual use. Such data will help inform FDA's regulation of, and product standards for, these and other tobacco products.

In developing this compliance period, FDA balanced three important public health considerations: Concern about the extended availability of newly deemed, new tobacco products without scientific review; concern about flavored products' youth appeal; and preliminary data that some individuals may potentially use such products to transition away from combusted tobacco use. Taking these factors into account, and based on currently available scientific evidence, FDA determined that the compliance periods described in Section V.A. strikes an appropriate balance to protect public health. FDA is establishing staggered compliance periods based on the expected complexity of the applications and continued compliance periods for FDA review such that our exercise of enforcement discretion will end twelve months after each initial compliance period. In addition, FDA is announcing that it intends in the future to issue a proposed product standard that would, if finalized, eliminate characterizing flavors in all cigars including cigarillos and little cigars.

Elsewhere in this issue of the **Federal Register**, FDA has made available draft guidance, which when final will describe FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products. FDA recognizes that flavored e-liquids are especially attractive to youth and young adults. Attractiveness to youth and young adults is an important factor in evaluating whether the marketing of a product is appropriate for the protection of the public health. Manufacturers should provide information on possible toxicity, addictiveness, and appeal of flavored tobacco products with their premarket review applications.

VI. Components, Parts, and Accessories

In the preamble to the NPRM, we asked for comments, including supporting facts, research, and other evidence, regarding FDA's proposal to include components and parts of the newly deemed products (but not accessories) under the scope of this rule. We also asked for comments as to whether FDA should define components and parts of tobacco products and how those items might be distinguished from accessories (79 FR 23142 at 23152 and 23153). After reviewing the comments, FDA is finalizing this rule to include components and parts of the newly deemed products (but excluding accessories of such products) within the scope of this rule. FDA is also explaining its current compliance policy with respect to components and parts and certain requirements that will become effective with this deeming rule.

A. Definitions

In response to comments, FDA is including definitions of "accessory" and "component or part" in parts 1100, 1140, and 1143. As stated in this final rule, an "accessory" means any product that is intended or reasonably expected to be used with or for the human consumption of a tobacco product; does not contain tobacco and is not made or derived from tobacco; and meets either of the following:

(1) Is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product, or

(2) Is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a tobacco product but (i) solely controls moisture and/or temperature of a stored product; or (ii) solely provides an external heat source to initiate but not maintain combustion of a tobacco product.

FDA has structured paragraph (2)(ii) to ensure that coils and charcoal are not encompassed by the definition of "accessory."

"Composition," as used in this definition, means the manner in which the materials, including, for example, ingredients, additives, and biological organisms, are arranged and integrated. Examples of accessories are ashtrays, spittoons, hookah tongs, cigar clips and stands, and pipe pouches, because they do not contain tobacco and are not derived from tobacco and do not affect or alter the performance, composition, constituents, or characteristics of a tobacco product. Accessory examples also include humidors that solely control the moisture and/or temperature of a stored product and a burner that solely provides an external heat source to initiate but not maintain combustion of a tobacco product. As stated in the NPRM, accessories of newly deemed products are not deemed with this final rule.

In addition, FDA is defining "component or part" to mean any software or assembly of materials intended or reasonably expected: (1) To alter or affect the tobacco product's performance, composition, constituents, or characteristics; or (2) to be used with or for the human consumption of a tobacco product. The definition excludes anything that is an accessory of a tobacco product.

We note that the term "material" means an assembly of ingredients, including additives. Materials are assembled to form components and parts. For example, material could be considered the glue or paper pulp for a cigarette where the paper pulp includes multiple ingredients (*e.g.*, multiple types of tobacco, water, and flavors) assembled into the paper (or pulp depending on the water content). A material could be considered the plastic in the mouthpiece of an ENDS containing multiple ingredients and additives assembled together to create a product.

In determining whether software or an assembly of materials might be "intended or reasonably expected" to alter or affect the tobacco product's performance, composition, constituents, or characteristics or to be used with or for the human consumption of a tobacco product (and, therefore, whether it is a component or part), FDA is not bound by the manufacturer or distributor's subjective claims of intent. Rather, FDA can consider the totality of the circumstances, including direct and circumstantial objective evidence, which encompasses a variety of factors such as circumstances surrounding the distribution of the product or the context in which it is sold (see, *e.g.*, 21 CFR 201.128 (drugs), 21 CFR 801.4 (devices); see also *U.S.* v. *Travia*, 180 F.Supp.2d 115, 119 (D.D.C. 2001)) and sales data.

Some examples of materials intended or reasonably expected to be used with or for the human consumption of a tobacco product are:

- Atomizers and cartomizers used with ENDS;
- water filtration base additives (including those which are flavored) used with waterpipe tobacco; and
- pouches or flavorings used with any of the newly deemed products (whether or not the pouch or flavoring contains nicotine or tobacco).

Some examples of materials intended or reasonably expected to alter or affect the tobacco product's performance, composition, constituents, or characteristics are:

- The cellophane wrapping or plastic tube for a single cigar;
- a plastic bag or tin holding loose pipe tobacco; and
- a glass or plastic vial container of e-liquid.

Although these examples are materials that are generally intended to prevent unintended changes to the characteristics of the tobacco product, they are also intended or reasonably expected to alter or affect the performance, composition, constituents, or characteristics of a tobacco product. For example, these materials often leach ingredients into the consumed product. As some comments noted, with ENDS, there is the potential for substances to leach from the containing vial into the e-liquid and these leachates may be inhaled when the e-liquids are used as intended, posing additional health risks for consumers. They often can also impact the moisture level or shelf life of a tobacco product (*e.g.*, whether a cigar is in a hard pack or soft pack, and whether pipe tobacco is in a plastic or metal container). The moisture level of a tobacco product, and changes to that moisture level, can, for example, significantly impact consumers' exposure to nicotine and other constituents. In some cases, menthol or other ingredients may have been applied to these materials in order to have them become incorporated into the consumed product.

FDA recognizes that in some circumstances some assemblies of materials can operate as both an aspect of the package and a component or part of the tobacco product. In such situations, the Agency is only examining a distinct subset of packaging materials that function as a component or part of a tobacco product by having the potential to alter or affect the tobacco product's performance, composition, constituents, or characteristics. Packaging materials that do not alter or affect, and are not reasonably expected to alter or affect, the tobacco product's performance, composition, constituents, or characteristics are not components or parts of a tobacco product. For example, a glass vial containing an e-liquid is a component or part of the tobacco product, whereas a hard plastic blister pack in which the glass vial of e-liquid is distributed and sold to consumers is not.

FDA intends to seek additional public comment and issue a rule or guidance to provide further clarification on assemblies of materials that are a "component or part" of a tobacco product because they are intended or reasonably expected to alter or affect the tobacco product's performance, composition, constituents, or characteristics or are intended or reasonably expected to be used with or for the human consumption of a tobacco product.

Many comments specifically asked for clarification and examples of which objects used with waterpipe tobacco would be considered components, parts, and accessories. The following is a nonexhaustive list of examples of components and parts used with waterpipe tobacco: Flavor enhancers; hose cooling attachments; water filtration base additives (including those which are flavored); flavored hookah charcoals; and bowls, valves, hoses, and heads. The following is a nonexhaustive list of objects used with waterpipe tobacco that would likely be considered accessories: Hookah glow balls, foil pokers, shisha oyster forks, tongs, and bags.

Many comments also sought clarification and examples as to which objects used with e-cigarettes would be considered components, parts, and accessories. The following is a nonexhaustive list of examples of components and parts of ENDS (including e-cigarettes): Atomizers, flavors used or intended to be used with ENDS (with or without nicotine), e-liquid solvents, tanks and tank systems, batteries (with or without variable voltage), coils, cartomizers, digital display/lights to adjust settings, clearomisers, and programmable software. The following is a nonexhaustive list of examples of objects used with e-cigarettes or other ENDS that would likely be considered accessories: Screwdrivers and lanyards.

A summary of comments regarding these issues, and FDA's responses, is included as follows.

(Comment 67) Many comments urged FDA to define components, parts, and accessories (particularly for e-cigarettes) to standardize enforcement nationally, prevent confusion in the marketplace (including among retailers), close any potential loopholes to circumvent compliance, increase transparency, and ensure inspectors are enforcing regulations, while also taking into account retailers who are making a good faith effort to comply with the law. Many comments provided suggested definitions for "component or part" and "accessory." Other comments stated that FDA should not define these categories of products, because it is too difficult to properly define such large categories of products and any definitions quickly would become outdated.

(Response) FDA agrees that definitions of component or part and accessory would be appropriate and has included definitions consistent with factors noted in the proposal and consideration of comments. Although we indicated in the NPRM that accessories are not expected to be used with or for consumption of a tobacco product, we also indicated our expectation that accessories will have little impact on the public health. While the definition of accessory is different than the description in the NPRM, based on consideration of the comments, it captures our original intent and the classes of products that the Agency views as accessories. The definitions of component, part, and accessory, which are discussed at the beginning of this section VI.A of the document, are included in §§ 1100.3, 1140.3, and 1143.1.

(Comment 68) Several comments expressed concern about FDA's statement in the NPRM that the Agency may consider rule revisions if FDA later decides to extend its regulatory authority to components and parts of newly deemed tobacco products that do not contain tobacco or nicotine. They stated that the Tobacco Control Act does not permit FDA to regulate such objects if they do not employ tobacco as a raw material.

(Response) FDA disagrees. To clarify, FDA is finalizing its proposal to deem all tobacco products, including all components and parts, but excluding accessories of newly deemed tobacco products, to be subject to chapter IX of the FD&C Act. However, the additional restrictions (*i.e.,* minimum age and identification, vending, and health warnings provisions) only apply to "covered tobacco products." The health warning provisions apply to "covered tobacco products," cigarette tobacco, and roll-your-own tobacco. The term "covered tobacco products" includes all newly deemed tobacco products except those components and parts that are not made or derived from tobacco.

FDA also disagrees that the FD&C Act does not authorize FDA to regulate products that do not employ tobacco as a raw material. Section 901 of the FD&C Act states that chapter IX of the FD&C Act applies to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary of Health and Human Services by regulation deems to be subject to chapter IX. Section 201(rr) of the FD&C Act defines "tobacco product," in relevant part, as any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). Therefore, the statute gives FDA authority to deem additional tobacco products, including all components, parts, and accessories, except for raw materials (other than tobacco) that go into manufacturing of components, parts, or accessories of a tobacco product. Examples of such raw materials would be unprocessed acacia gum (taken from a tree and not processed) and minted titanium dioxide (used for whitening cigarette and tipping paper). In this rule, FDA is not deeming accessories to be subject to chapter IX and, although it is deeming all components and parts to be subject to chapter IX, it is not applying the additional restrictions (*i.e.,* minimum age and identification, vending, and health warnings provisions) to components and parts that are not made or derived from tobacco. Nevertheless, if FDA were to consider extending its authority to accessories or to apply additional restrictions to components or parts, FDA would do so through the rulemaking process.

(Comment 69) A few comments expressed concern that the rule would create incentives for manufacturers to separate nicotine-containing components from nonnicotine-containing components to evade regulatory requirements. They stated that the rule would allow minors to purchase nicotine delivery systems, as long as they do not contain e-liquids, and obtain the e-liquids from other sources (*e.g.,* friends, parents, online).

(Response) FDA understands these concerns. However, this deeming rule covers tobacco product components and parts intended or reasonably expected to be used with or for the human consumption of a tobacco product. In addition, as stated in § 1140.16, retailers of newly deemed tobacco products may not sell covered tobacco products (through any medium, including the Internet) to individuals under 18 years of age. FDA will continue to actively enforce the minimum age restriction for mail order and Internet sales, which will help to reduce youth access to the nicotine and tobacco containing components, without which they cannot use the other components of ENDS.

(Comment 70) Some comments stated that the objects used in or with an e-cigarette (including batteries, wire, screws, silica) should be beyond the scope of FDA's authority, because they do not become part of the tobacco product until they are constructed by the consumer. Others stated that FDA should regulate these objects given reports regarding the malfunctioning of certain e-cigarette components (*e.g.*, dangers of exploding batteries (Ref. 65)) and the fact that the e-liquid cannot be consumed without each component working in conjunction to deliver nicotine to the consumer. These comments asked FDA to clarify whether the Agency will regulate only the nicotine-containing cartridges in a line of products that includes varying degrees of nicotine including cartridges advertised as nicotine free if they are intended to be used with or for the human consumption of a tobacco product.

(Response) This final deeming rule deems all tobacco products as they are defined in section 201(rr) of the FD&C Act, except accessories of newly deemed products, but including components and parts as defined in this rule. The wires, screws, and silica meet the definition of component or part, as they are an assembly of materials intended or reasonably expected to be used with or for the human consumption of a tobacco product and are not accessories of a tobacco product. FDA also remains concerned about reports of exploding batteries. Batteries that are co-packaged with other components or parts of an ENDS (*e.g.*, cartridges and tanks) or otherwise intended or reasonably expected to be used with or for the consumption of ENDS are components or parts and subject to FDA's tobacco product authorities. However, as noted elsewhere in this document, for ENDS hardware or delivery system components or parts, such as batteries, FDA expects that it may be difficult for manufacturers to obtain premarket authorization for such products, given the great extent of possible variations in combinations of hardware components, if all considered and sold separately. Thus, with respect to such apparatus, FDA expects that manufacturers will be most successful where authorization is sought for entire delivery systems, rather than individual components. Elsewhere in this issue of the **Federal Register**, FDA also has made available draft guidance, which when final will represent some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products and will include FDA's current thinking regarding compliance with existing voluntary standards for ENDS batteries.

In addition, nicotine-containing cartridges that include varying degrees of nicotine are components or parts and subject to FDA's chapter IX authorities because they constitute an assembly of materials intended or reasonably expected to be used with or for the human consumption of a tobacco product and do not constitute a tobacco product accessory. Upon the effective date of this final rule, FDA intends to regulate the entire line of cartridges (including cartridges that include varying degrees of nicotine or those that do not contain nicotine, if they meet the definition of component or part).

(Comment 71) Several comments urged FDA to include all e-liquids in the minimum age and identification requirements and vending machine restrictions in the revised part 1140, including e-liquids that do not contain nicotine, because they are easily accessible to minors online and can be mixed with nicotine. In addition, they suggested that FDA require the proposed addiction warning on all components or parts sold in conjunction with e-liquid.

(Response) FDA disagrees. Under this deeming rule, e-cigarettes that contain nicotine cannot be sold to youth under the age of 18. In addition, an e-liquid with nicotine is a covered tobacco product and, therefore, will be required to have a health warning under part 1143. As previously discussed, an e-liquid without nicotine is a component (and subject to FDA's tobacco control authorities), if it is intended or reasonably expected to be used with or for the human consumption of a tobacco product (*e.g.*, with liquid nicotine) and does not constitute a tobacco product accessory, but an e-liquid that does not contain nicotine or tobacco is not required to carry a warning, nor is it subject to the minimum age and identification requirements and vending machine restrictions under parts 1140 and 1143 because it is not a covered tobacco product as defined by this rule. Because components without nicotine or tobacco are intended to be used with a covered tobacco product, which contains nicotine or tobacco, FDA believes that it is appropriate to require only the covered tobacco product to be subject to the minimum age and vending machine provisions and to carry the warning. Moreover, if a warning is overused, there is the danger that it will grow stale.

(Comment 72) One comment disagreed with what it characterized as FDA's assertions that tobacco product accessories do not pose a public health risk or environmental risk and stated that such objects are harmful to humans and the food chain.

(Response) FDA wishes to clarify language included in the NPRM regarding accessories (79 FR 23142 at 23153). FDA did not propose, nor is it stating in this final rule, that tobacco product accessories do not pose any public health risk. Instead, we indicated that tobacco product accessories as defined in the rule likely have less (rather than "no") risk to the overall public health, which we reiterate in this final rule. FDA is regulating components and parts (and not accessories) of the newly deemed products, so the Agency can better focus its resources on those objects with a greater likely impact on public health. Similarly, FDA did not state that this rule would not impact the environment. Rather, the environmental analysis included in the NPRM stated that the impacts of this rule will not have a significant impact on the human environment according to the standard imposed by the National Environmental Policy Act, as stated in the proposed environmental assessment (EA). The final EA and Finding of No Significant Impact (FONSI) are included in the docket.

(Comment 73) The comments suggested several different regulatory approaches for components, parts, and accessories. First, several comments stated that FDA should weigh the relative risks of these products and impose the least burdensome requirements necessary to effectively manage or mitigate those risks. They suggested that FDA treat these products the way the Agency does with its review of marketing applications. For example, they noted that FDA's draft and final guidance documents on PMTAs and SE reports explain that FDA does not intend to enforce the requirements of either section 910 or 905(j) of the FD&C Act for components of regulated tobacco products that are sold or distributed solely for further manufacturing into finished tobacco products because the Agency anticipates "receiving relevant information regarding such new tobacco products in the PMTA submission for the finished regulated tobacco products" (citing draft guidance, "Applications for Premarket Review of New Tobacco Products"). Second, some comments believed that manufacturers of e-cigarette components and parts should be required to submit marketing applications given the aerosols and "vapors" that consumers generate when using certain components or parts. Third, some comments stated that instead of requiring manufacturers of components and parts to comply with the automatic requirements for the newly deemed products, FDA should require them to ensure that all of their components and parts that contain tobacco or tobacco derivatives are shipped and packaged with labeling that indicates that they are intended for further manufacture.

(Response) At this time, FDA intends to limit enforcement of the premarket review requirements to finished tobacco products. For purposes of this compliance policy applicable to newly deemed products, a finished tobacco product refers to a tobacco product, including all components and parts, sealed in final packaging intended for consumer use (*e.g.*, filters or filter tubes sold separately to consumers or as part of kits). FDA does not at this time intend to enforce these requirements for components and parts of newly deemed products that are sold or distributed solely for further manufacturing into finished tobacco products. In addition, FDA does not believe that it is warranted at this time to require components and parts that contain tobacco or tobacco derivatives to include labeling that indicates they are intended for further manufacture.

(Comment 74) Some comments stated that FDA should regulate all components, parts, and accessories, as long as they have a foreseeable impact on the public health. They believed that omitting accessories from the scope of the deeming rule ignores the clear statutory language that explicitly defines "tobacco product" to include accessories.

(Response) FDA disagrees. Although Congress included "accessories" within the definition of "tobacco product" in section 201(rr) of the FD&C Act, it did not explicitly require that FDA include all components, parts, and accessories within the scope of its rule to deem additional tobacco products under section 901. Accessories, as defined in this rule, likely have less risk to the overall public health, and the benefits to overall public health for deeming accessories subject to FDA's tobacco product authorities are also likely less. Therefore, FDA is excluding them from the scope of this deeming rule.

(Comment 75) Some comments stated that items also used for purposes other than for tobacco use (*i.e.*, a lighter or matches that can be used to light candles) should be classified as accessories and, therefore, not subject to FDA's chapter IX authorities. For example, batteries used in advanced personal vaporizers can be found in laptop battery packs or cordless drill packs. These comments also stated that items such as lighters and batteries may (or may not) be used in consumption of a tobacco product or are regulated by the Consumer Product Safety Act (as are child-resistant lighters) and, therefore, should not be subject to FDA's tobacco product authorities.

(Response) FDA agrees that it is not necessary to regulate batteries that are not intended or reasonably expected to be used with a tobacco product under its tobacco product authorities. However, it is important that batteries that are co-packaged with other parts of an ENDS (*e.g.*, cartridges and tanks) or otherwise intended or reasonably expected to be used with ENDS are components subject to FDA's tobacco product authorities. FDA remains concerned about reports of exploding e-cigarette batteries and finds that regulating them can help address these problems. Toward that end, elsewhere in this issue of the **Federal Register**, FDA has made available draft guidance, which when final will describe FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products, including compliance with existing voluntary standards for ENDS batteries.

(Comment 76) Some comments stated that walk-in humidors for cigars should not be subject to FDA regulation because they are important to retailers and allow consumers to browse a retailer's stock and make a selection.

(Response) As discussed previously, any item that is intended or reasonably expected to be used with or for the human consumption of a newly deemed tobacco product; does not contain tobacco or a tobacco derivative; and is intended or reasonably expected to affect or maintain the characteristics of the newly deemed tobacco product but solely controls moisture and/or temperature of a stored newly deemed tobacco product, is an accessory and excluded from this deeming rule. Therefore, unless the humidor is designed to affect the tobacco product in a manner other than controlling moisture or temperature, such walk-in cigar humidors are not subject to this rule.

(Comment 77) A few comments expressed concern that e-cigarette tanks and cartridges would not be included within the proposed vending machine restrictions because they do not contain nicotine at the time of sale. They said that such objects are not standardized and that their quality, composition, and safety are not regulated and, therefore, they should be subject to FDA's chapter IX authorities.

(Response) FDA does not believe it is necessary for tanks and cartridges that do not contain nicotine or tobacco to be subject to the vending machine restrictions because they can only be used to consume tobacco or nicotine derived from tobacco with other products that are subject to the additional restrictions. However, FDA is aware of the current lack of regulation or standardization of tanks and cartridges, which are components and parts that FDA is deeming to be subject to FDA's chapter IX authorities with this rule. After the effective date of this final rule, FDA will have authority to issue tobacco product manufacturing practice regulations under section 906(e) of the FD&C Act and product standards under section 907 of the FD&C Act to address the quality, composition, and safety of these components and parts. FDA also notes that these components and parts will usually be subject to premarket review, either by themselves, as components and parts intended for consumer use, or as components and parts of products that undergo further manufacturing for which the end product will be subject to premarket review.

(Comment 78) A few comments expressed concern with FDA's characterization of objects used during a waterpipe tobacco session (*i.e.*, the burners, holders, screens, and other objects used with waterpipe tobacco). They stated that all waterpipe burners and holders can affect waterpipe tobacco emissions, and noted that foil is heated to the same extent as charcoal during waterpipe use and, therefore, can present a burning danger (Ref. 66). In addition, the heating source, screen (or aluminum foil), and hose can have a significant impact on passive and active exposure and smoking/puffing behaviors and, therefore, should be components or parts subject to chapter IX of the FD&C Act.

(Response) FDA has included definitions of "component," "part," and "accessory" with this final rule to provide additional clarity regarding the characterization of products used during a waterpipe session. According to these definitions, the screen (or aluminum foil) and hoses that are co-packaged with other parts of a hookah or marketed, advertised, or otherwise intended for use with a hookah are parts or components and subject to FDA's tobacco product authorities. However, for example, an external burner or heating source that is not incorporated into the hookah would be an accessory, provided that it does not contain tobacco or a tobacco derivative and solely provides an external heat source to initiate but not maintain combustion of a tobacco product. The holder also is an accessory and not subject to chapter IX of the FD&C Act.

(Comment 79) A few comments suggested that charcoal or wood cinder used with waterpipe tobacco should be considered a tobacco product and deemed under this regulation. They explained that combustion of these products produces toxicants and may emit carcinogens, carbon monoxide, polycyclic aromatic hydrocarbons, and other cancer causing agents.

(Response) FDA finds that such products are components or parts; therefore, they are subject to FDA's chapter IX authorities. They are an assembly of materials intended or reasonably expected to be used with or for the human consumption of a tobacco product and are not accessories. As we have noted throughout this document, an accessory does not contain tobacco and is not made or derived from tobacco, and it meets one of the following: (1) Is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product; or (2) is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a tobacco product but (i) solely controls moisture and/or temperature of a stored product; or (ii) solely provides an external heat source to initiate but not maintain combustion of a tobacco product. Therefore, the charcoal or wood cinder intended or reasonably expected to be used with or for the human consumption of waterpipe tobacco are components or parts. Further, charcoal and wood cinders are not considered accessories given that they: (1) Do not contain tobacco and are not made or derived from tobacco; and (2) are intended or reasonably expected to alter the characteristics of a tobacco product but do not solely control moisture and/or temperature of a stored product and do not solely provide an external heat source to initiate but not maintain combustion. Instead, both charcoal and wood cinder are used to maintain the combustion of waterpipe tobacco.

(Comment 80) Many comments asked for clarification as to whether certain items associated with cigar use should be termed "accessories," including cigar tip cutters, permeable humidor buttons, removable tips, mouthpieces, removable filters, holders, lighters, ashtrays, and cases.

(Response) FDA generally expects cigar tip cutters, permeable humidor buttons, holders, ashtrays, and cases would be accessories that are not subject to FDA regulation. In addition, as stated in this section (discussing the definitions of component or part and accessory), for the purposes of this regulation, any item that does not contain tobacco or a tobacco derivative and is not integrated in a tobacco product, but rather solely provides an external heat source, to initiate but not maintain combustion of a tobacco product (such as a lighter) is not subject to this deeming rule. However, removable tips, mouthpieces, and filters are all intended to be used by adult consumers in the human consumption of a tobacco and do not meet the definition of accessory, therefore, are included within the scope of this final rule.

(Comment 81) A few comments expressed concern that vaporizers sold separately without nicotine can be modified or "hacked," which researchers found could increase toxins and other dangerous components, including formaldehyde (Ref. 67). They stated that online videos show how to "hack" an e-cigarette, including how to change the apparatus to increase the temperature of the "vapor." Because of these concerns, they argued that such items should be considered components and parts and under FDA's jurisdiction.

(Response) FDA agrees that vaporizers are components or parts of a tobacco product. These objects are an assembly of materials intended or reasonably expected to be used with or for the consumption of a tobacco product and do not constitute tobacco product accessories. Therefore, they are tobacco product components or parts and subject to FDA's chapter IX authorities. FDA considers components or parts sold directly to consumers to be finished tobacco products. A finished tobacco product refers to a tobacco product, including all components and parts, sealed in final packaging intended for consumer use (*e.g.*, filters or filter tubes sold separately to consumers or as part of kits). FDA remains concerned about adverse events associated with ENDS use and finds that regulating them can help address these problems. Toward that end, elsewhere in this issue of the **Federal Register**, FDA has made available draft guidance, which when final will describe FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products.

(Comment 82) One comment requested that flavored rolling papers be included as a newly deemed tobacco product. Another comment claimed that flavored papers should not be subject to FDA's tobacco control authorities, because they do not pose a danger to public health.

(Response) Rolling papers intended for use with cigarette tobacco or roll-your-own tobacco are already subject to FDA's tobacco control authorities under section 901 of the FD&C Act because they are components of cigarettes and cigarette tobacco. Upon the effective date of this final rule, rolling papers (including flavored papers) intended for use with newly deemed tobacco products would be tobacco product components or parts and subject to FDA's chapter IX authorities.

B. Discussion of Requirements Associated With Components and Parts

FDA received many inquiries about how the automatic provisions associated with deeming tobacco products would apply to components and parts. Components and parts of newly deemed tobacco products are subject to all of the automatic provisions included in the FD&C Act, as further discussed as follows.

1. Ingredient Listing (Sections 904(a)(1) and 904(c)); Health Document Submission (Section 904(a)(4)); and Registration and Product Listing (Section 905)

At this time, FDA intends to limit enforcement to finished tobacco products. A finished tobacco product refers to a tobacco product, including all components and parts, sealed in final packaging intended for consumer use (*e.g.*, filters, filter tubes, e-cigarettes, or e-liquids sold separately to consumers or as part of kits). FDA does not at this time intend to enforce these requirements for components and parts of newly deemed products that are sold or distributed solely for further manufacturing into finished tobacco products.

2. SE Reports and PMTAs (Section 905(j) and 910)

At this time, FDA intends to limit enforcement to finished tobacco products. FDA does not at this time intend to enforce these requirements for components and parts of newly deemed products that are sold or distributed solely for further manufacturing into finished tobacco products.

3. Reporting of HPHCs (Section 915)

At this time, FDA intends to limit enforcement to finished tobacco products. See section IX for further discussion of ENDS retail establishments and the responsibilities of upstream manufacturers for reporting of HPHCs. The Agency is working to determine an appropriate compliance policy to deal with HPHCs for newly deemed products (including e-liquids) and is intending to issue guidance with enough time for manufacturers to report given the 3-year compliance period.

VII. Regulation of Cigars and Selection of Option 1

As discussed in the preamble to the NPRM (79 FR 23142 at 23150 through 23152), it has been suggested that different kinds of cigars may have the potential for varying effects on public health. Accordingly, FDA proposed two options for the categories of cigars to be subject to this deeming rule. Option 1 proposed to deem all products meeting the statutory definition of "tobacco product," except accessories of a proposed deemed tobacco product, to be subject to FDA's tobacco product authorities under chapter IX of the FD&C Act. Option 2 proposed to deem all products meeting the statutory definition of "tobacco product," except accessories of a proposed deemed tobacco product and a subset of cigars referred to as "premium cigars" to be subject to FDA's tobacco product authorities under chapter IX of the FD&C Act. FDA notes that individual hand rollers of cigars would be considered manufacturers under chapter IX of the FD&C Act, and subject to the same requirements as other tobacco product manufacturers.

(Comment 83) Some comments that supported Option 1 stated that FDA should regulate premium cigars, in part, because they meet the statutory definition of "tobacco product."

(Response) FDA agrees. All cigars, including those referred to as premium cigars, meet the definition of a "tobacco product" under section 201(rr) of the FD&C Act.

After thorough review of the comments and the scientific evidence, FDA has concluded that deeming all cigars, rather than a subset, more completely protects the public health and therefore has adopted Option 1 in the final rule. FDA has concluded that: (1) All cigars pose serious negative health risks, (2) the available evidence does not provide a basis for FDA to conclude that the patterns of premium cigar use sufficiently reduce the health risks to warrant exclusion, and (3) premium cigars are used by youth and young adults. The fact that some premium cigar smokers might smoke such products infrequently or report that they do not inhale does not negate the adverse health effects of tobacco smoke or demonstrate that cigars do not cause secondhand smoke-related disease in others. Therefore, we find there is no appropriate public health justification to exclude premium cigars from the scope of the final deeming rule and that it is appropriate to deem them.

A. Health Risks of Premium Cigars

Researchers estimate that regular cigar smoking was responsible for approximately 9,000 premature deaths or almost 140,000 years of potential life lost among adults 35 years or older in 2010 (Ref. 68). Cigar smoke contains many of the same harmful constituents as cigarette smoke and may have higher levels of several harmful compounds (Ref. 68, citing Ref. 69 at 55–104). All cigar smokers have an increased risk of oral, esophageal, laryngeal, and lung cancer compared to non-tobacco users (Refs. 35, 69). Among those who report inhaling cigar smoke, there are significantly elevated levels of many types of cancer and other adverse health effects, such as increased risk of heart and pulmonary disease (Refs. 69, 70). Cigar smokers also are at a marked increase in risk for chronic obstructive pulmonary disease (COPD) and experience higher mortality risk from COPD than nonsmokers (Refs. 70, 71). In addition, cigar smokers have a higher risk of fatal and nonfatal stroke than nonsmokers (Ref. 72). All cigars produce secondhand smoke, which causes negative health effects such as heart disease and lung cancer in bystanders (Refs. 35, 69).

Nevertheless, we do note that the 2014 Surgeon General's Report states that when compared with persons who smoke cigarettes, those who use cigars exclusively have a lower risk for many smoking-related diseases (Ref. 9 at 428 citing Ref. 69). Although smoke from cigars contains the same toxic substances as cigarette smoke, cigar smokers generally smoke at a lower frequency and tend not to inhale the smoke, thus reducing (but not eliminating) their exposure to its toxic substances (id.). Former cigarette smokers are more likely to inhale cigar smoke than are primary cigar smokers who have never smoked cigarettes (id.).

While most studies cited in this section do not explicitly pertain to premium cigars, the bulk of the established data on the health effects of cigar smoking is based on smokers of traditional, large cigars and, therefore, is applicable to the toxicity of premium cigars given that they share the same characteristics and are generally smoked in similar ways.

While exposure to higher levels of cigar smoke for a longer period of time increases the adverse health risks due to cigar smoking (just as it does for cigarettes), the Surgeon General has stated that no amount of smoking is safe (Ref. 2). Further, there are no data indicating that premium cigar users are not susceptible to health risks, as discussed in section VII.C. FDA's responses to comments on the health risks of premium cigars are included in the following paragraphs.

(Comment 84) Proponents of Option 1 stated there is no public health justification for exempting premium cigars and that deeming premium cigars will benefit the public health immediately through the automatic and additional provisions and the imposition of future product standards. They also stated that exempting premium cigars would have a negative impact on the public health.

(Response) FDA agrees. As stated in the NPRM, there will be many public health benefits associated with deeming tobacco products (including products referred to as premium cigars). For example, the adulteration and misbranding provisions in sections 902 and 903 of the FD&C Act, as applied to the newly deemed products, will protect consumers because FDA will be able to take enforcement action against any non-compliant tobacco product, such as a product with false or misleading labeling or advertising. In addition, ingredient listings and reports of HPHCs under sections 904 and 915 of the FD&C Act will assist FDA in better understanding the contents of regulated products. That information would assist FDA in assessing potential health risks and determining if future regulations to address the health risks posed by particular products are warranted. With application of the section 905 registration and listing requirements, FDA will be able to conduct biennial inspections of tobacco product manufacturers. Further, implementation of the premarket review provisions of sections 905, 910, and 911 of the FD&C Act will allow FDA to monitor product development and changes and to prevent more harmful or addictive products from reaching the market. Moreover, there were no data provided to support the premise that there are different patterns of use of premium cigars and that these patterns result in lower health risks.

(Comment 85) Some comments argued that exempting premium cigars from deeming would set a dangerous precedent that it is appropriate for FDA not to regulate certain tobacco products by virtue of their potential for varying effects on public health. An exemption could mislead consumers to believe that premium cigars are safe, which contradicts the available evidence that all cigars are harmful and potentially addictive. In addition, the current population of premium cigar users would be left unprotected, potentially decreasing the likelihood that they would quit, and leading more youth and young adults to initiate use of premium cigars or substitute products.

(Response) FDA agrees with these comments. Accordingly, FDA has selected Option 1 deeming all cigars, rather than a subset, for the scope of this final rule.

(Comment 86) Many comments that supported Option 2 argued that premium cigars do not present a public health threat significant enough to warrant regulation and that no evidence was presented that regulation of premium cigars would substantially improve the public health. These comments stated that premium cigars represent a small portion of the tobacco product and cigar markets (annual premium cigar estimate in the United States of 300 million units compared to nearly 14 billion total cigar units and nearly 300 billion cigarettes) (Ref. 73), and there is no evidence that premium cigars have the same health consequences or habitual use patterns as other tobacco products. They generally relied on two studies, Funck-Brentano et al. and Turner et al., to claim that premium cigars deliver little nicotine to users, by inhalation or oral absorption (Refs. 74, 75). They also claimed that cigars do not significantly elevate the risk of addiction or death (Refs. 76, 77) and stated that, in some studies, there were a very small number of cancer cases or deaths among cigar smokers (Refs. 78, 79). They also noted the nonsignificant odds ratios for those consuming 1 to 2 cigars per day (Refs. 69, 79) and for the risk of lung cancer and "tobacco-related cancers" among exclusive cigar smokers (Ref. 80).

(Response) FDA disagrees with these claims and finds that the cited studies or critiques are not persuasive. Regarding the claim that premium cigars deliver little nicotine to users, the Turner study (Ref. 75) was a study of only 10 male hospital workers conducted more than 30 years ago. The findings of the Turner study, based on carboxyhemoglobin and plasma nicotine levels, suggested that former cigarette smokers who occasionally smoked cigars or regularly smoked pipes had greater cigar smoke inhalation and absorption than primary cigar and pipe smokers (*i.e.,* those who never smoked cigarettes). This study also reported that average plasma nicotine concentrations among primary cigar and pipe smokers were somewhat elevated 60 minutes into a cigar smoking session compared with levels measured after smoking abstinence (Ref. 75). Notwithstanding the small sample size, the study results still demonstrate that cigars deliver nicotine to users.

Similarly, the Funck-Brentano et al. study (Ref. 74) assessed biomarkers of tobacco exposure and toxicity in a small sample of cigar (corona-sized or larger cigar) or pipe smokers (n = 30), cigarette smokers (n = 28), and nontobacco users (n = 30), making this small biomarker study less persuasive. In fact, the study authors state: "These results should not be seen as a justification for the smoking of pipes and cigars, which are clearly associated with clinically significant health hazards. We emphasize that we cannot determine whether our results are explained by the type of tobacco smoked or by the different inhalation pattern in pipe/cigar smokers and cigarette smokers."

A recent analysis of biomarkers of tobacco exposure among cigar smokers used data from the 1999–2012 National Health and Nutrition Examination Survey, a nationally representative survey (Ref. 81). The sample included more than 220 primary cigar (*i.e.,* current cigar/never cigarette) smokers and more than 180 secondary cigar (*i.e.,* current cigar/former cigarette) smokers (id.). The researchers found that serum cotinine concentrations among primary (and secondary) cigar smokers were substantially higher than in nontobacco users in crude and adjusted analyses (id.). In addition, adjusted analyses showed that concentrations of NNAL (4-(methylnitrosamino)-1-(3-pyridyl)-1-butanol), blood cadmium, and lead were also higher among primary (and secondary) cigar smokers compared with nontobacco users (id.). Therefore, not only were the cited studies unpersuasive, but this robust and recent analysis contradicts those studies.

In addition, FDA did not find persuasive studies cited in comments for the proposition that cigars do not significantly elevate the risk of addiction or death. To support this proposition, comments relied in part on a study (Ref. 76) in which a panel scored the worldwide harmfulness of 12 nicotine products using a multicriteria decision analysis approach. Although cigarettes ranked higher than either little cigars and other cigars on an aggregate harm score, the study found cigar smoking does result in morbidity, mortality, and dependence.

The other study used to support the proposition that cigars are not a significant public health threat (Ref. 77) found a significant association between primary cigar or pipe smokers and lung cancer mortality risk, which refutes the claim that cigar use does not significantly elevate the risk of death. In addition, this study found an association between COPD mortality risk and secondary cigar or pipe smoking (but not for primary cigar and pipe smoking). Also, contrary to the assertions of commenters, a recent systematic review of cigar smoking and mortality summarized the results of 22 published studies from 16 different prospective cohorts and found that primary cigar smoking was associated with increased risk of mortality from all causes, several types of cancers, coronary heart disease, and aortic aneurysm (Ref. 82). Mortality risks were greater with increasing number of cigars smoked per day and self-reported level of inhalation, however, primary cigar smokers reporting no inhalation still had highly elevated mortality risks for oral, esophageal, and laryngeal cancers (id.). In addition, a recent study estimated that in 2010 more than 9,000 premature deaths annually were attributable to regular cigar smoking (*i.e.,* those who reported smoking cigars on at least 15 of the past 30 days) (Ref. 68).

Moreover, FDA reviewed a study by Boffetta et al. (Ref. 78), which commenters relied upon to claim that a very small number of cancer cases existed among cigar smokers and, therefore, premium cigars should not be regulated. The Boffetta et al. study (id.) used a case-control design to assess the association between lung cancer risk and cigar smoking. The authors determined that the overall association between primary cigar or cigarillo smokers and lung cancer was significant and found significant associations in all but one area (id.). For all other estimates, the results were statistically significant. We also note that, despite the relatively small number of cancer cases in this study, it is only one part of a larger body of evidence that demonstrates the increased risk of serious adverse health effects associated with cigar smoking (Refs. 35, 69, 70, 71, 72, 77, 79, 83).

(Comment 87) Some comments stated cigar smokers are not at risk of becoming addicted to tobacco products based on their use of cigars. Other comments stated that certain attributes of premium cigars increase the likelihood for nicotine dependence, including their size, the amount of tobacco (and, therefore, nicotine) in the cigar, and the longer amount of time that it takes to smoke the cigar.

Additionally, these comments suggested that because cigar tobacco is more alkaline than cigarette tobacco, nicotine may be absorbed into the blood stream more rapidly, even without inhaling (Refs. 84, 85).

(Response) FDA agrees that all cigars are potentially addictive. As discussed in the preamble to the NPRM, a cigar can contain as much tobacco as a whole pack of cigarettes, and nicotine yields from smoking a cigar can be up to eight times higher than yields from smoking a cigarette (79 FR 23142 at 23154). Although the amount of nicotine taken in by a cigar user depends on various factors like how long the person smokes the cigar, the number of puffs taken, and the degree of inhalation, a leading review of the science of cigar smoking concluded that "[c]igars are capable of providing high levels of nicotine at a sufficiently rapid rate to produce clear physiological and psychological effects that lead to dependence, even if the smoke is not inhaled" (Ref. 35). In addition, regardless of whether premium cigar smokers inhale, buccal absorption of nicotine does occur, and cigar smokers may also absorb nicotine through the lips due to the alkalinity of cigar tobacco (Refs. 86, 87). This increased nicotine yield and absorption increases the risk of nicotine addiction from cigar smoking. Researchers analyzing data from the NYTS found that although the percentage of youth reporting various measures of dependence was lower for cigars than for cigarettes or smokeless tobacco, some youth did report some measures of cigar addiction (Ref. 88). This study found that 6.7 percent of middle and high school students who only smoked cigars also reported strong cravings for a tobacco product during the past 30 days, and 7.8 percent reported sometimes/often/always feeling irritable or restless when not using tobacco—which are measures of dependence (id.) We note that the Surgeon General has found that all forms of nicotine delivery do not pose an equal risk in establishing or maintaining nicotine addiction (Ref. 9).

(Comment 88) Many comments remarked that premium cigars do not pose the same adverse health effects as cigarettes and other types of cigars because most studies of cigar health effects do not differentiate between types of cigars. They claimed this lack of evidence precludes conclusions about the health effects of premium cigars specifically.

(Response) The science is clear that cigar use of all types can lead to negative health effects, as discussed throughout this section of the document. Thus, the contention that studies are inconclusive about the health effects of premium cigars because they do not differentiate between types of cigars is not persuasive.

All cigar use is harmful and potentially addictive. Cigar smokers have an increased risk of oral, esophageal, laryngeal, and lung cancer compared to nonsmokers (Refs. 35, 69). Among those who report inhaling cigar smoke, there are significantly elevated levels of many types of cancer and other health effects, such as increased risk of heart and pulmonary disease (Refs. 69, 70). Cigar smokers also have a marked increase in risk for COPD and experience higher mortality risk from COPD than nonsmokers (Refs. 70, 71). In addition, cigar smokers have a higher risk of fatal and nonfatal stroke than nonsmokers (Ref. 72). All cigars produce secondhand smoke, which causes negative health effects such as heart disease and lung cancer in bystanders (Refs. 35, 69).

We note that the Surgeon General reported in 2014 that, "[c]ompared with persons who smoke cigarettes, smokers who smoke pipes or cigars exclusively have a lower risk for many smoking-related diseases (internal citation omitted). Smoke from pipes and cigars contains the same toxic substances as cigarette smoke, but those who use a pipe or cigar usually smoke at a lower frequency; observation indicates that they tend not to inhale the smoke, thus reducing their exposure to its toxic substances (internal citations omitted). Evidence indicates that former cigarette smokers are more likely to inhale pipe or cigar smoke than are primary pipe and cigar smokers who have never smoked cigarettes (internal citations omitted)" (Ref. 9 at 428–429). However, research indicates that most cigar smokers do inhale some amount of smoke, even when they do not intend to inhale, and are not aware of doing so (Refs. 32, 33).

Finally, FDA specifically sought comment on how the potential different patterns of use for premium cigars might result in different or decreased health impacts, but no such evidence was submitted (see discussion in section VII.C of document).

(Comment 89) Some comments indicated that many cigar users, including those who smoke premium cigar brands, are also current or former cigarette users, increasing their exposure to toxic constituents and the health risks of using combusted tobacco products (Refs. 89, 90). Additionally, they stated that these users are more likely to inhale when they use cigars and may smoke more cigars per day, significantly increasing their health risks (Refs. 33, 91, 92, 93, 94).

(Response) FDA agrees. Given the adverse health effects of all cigars, FDA has selected Option 1 deeming all cigars, rather than a subset, for the scope of this final deeming rule.

(Comment 90) Some comments raised concerns about dual and polyuse of cigars and other tobacco products, which is common among both adults and youth (Refs. 90, 95). For example, in one study, 35.1 percent of adult premium cigar users, 58.3 percent of cigarillo and other mass market cigar users (*i.e.*, those reporting their usual cigar did not have a filter and the usual brand was not premium), and 75.2 percent of little filtered cigar users also smoked cigarettes (Ref. 90). Some comments noted that multiple product use is concerning because polytobacco users are more likely to report symptoms of nicotine dependence (Ref. 88).

(Response) As FDA stated in the NPRM, we are concerned about the use of multiple products, especially combusted tobacco products.

B. Youth and Young Adults Use Premium Cigars

Proponents of Option 2 have stated that an exemption for premium cigars is warranted because youth prefer machine-made cigars (as opposed to hand-rolled) given their low price, flavoring, and easier availability. However, although youth and young adults have a higher use of cigarillos and other mass market cigars, studies indicate that they are also using premium cigars.

(Comment 91) Many comments cited data showing that among those age 12 and older, past month cigar use decreased slightly from 5.4 percent in 2002 to 5.2 percent in 2012 after peaking at 5.7 percent in 2004 (Ref. 89 at Figure 4.1). Among youth only (ages 12 to 17), cigar smoking prevalence declined between 2004 (4.8 percent) and 2012 (2.6 percent) (Ref. 89 at Figure 4.1). Trend data from the National Youth Risk Behavior Survey also indicate that cigar use among male high school students, female students, and white, black, and Hispanic students either declined or remained stable from 1997 to 2011 (Ref. 9). Additionally, from 1997 to 2013, "a significant linear decrease occurred overall in the prevalence of current [youth] cigar use (22.0 percent–12.6 percent)" (Ref. 96), which was observed from data collected by the CDC 1997–2013 YRBS (Ref. 29). Accordingly, they questioned whether FDA should be regulating cigars.

Other comments included data indicating that youth cigar use has not declined when compared to use of other tobacco products. They noted that many youth surveys show youth cigar smoking to be higher than, or about the same as, cigarette smoking. For example, in 2013, among U.S. high school males, the prevalence of current (past 30 day) cigar smoking (16.5 percent) was comparable to current (past 30 day) cigarette smoking (16.4 percent) (Ref. 96). Additionally, in 21 U.S. cities that conducted the 2013 YRBS, the prevalence of current cigar smoking (8.6 percent) was comparable to current cigarette smoking (7.7 percent) among high school students (id.). In 2014, NYTS reported that among high school Non-Hispanic black students, 8.8 percent reported smoking cigars in the past 30 days, whereas 4.5 percent reported smoking cigarettes in the past 30 days (Ref. 22). In addition, among high school males overall, the prevalence of past 30 day cigar smoking (10.8 percent) was comparable to past 30 day cigarette smoking (10.6 percent) (id.). Measures of youth use of cigars may underestimate prevalence due to incorrect self-identification as a non-cigar smoker and confusion between the various cigar products (Refs. 97, 98, 99). Accordingly, the comments supported FDA's regulation of all cigars.

(Response) FDA remains concerned about the use of all tobacco products, particularly combusted tobacco products like cigars and cigarettes, and remains most concerned about use by youth and young adults given their *unique* susceptibility to the addictiveness of nicotine. Although supporters of Option 2 relied upon NSDUH data showing a decline in cigar smoking prevalence among individuals aged 12 to 17 from 2004 to 2012, the NSDUH's questions about ever and past 30-day use of cigars did not include examples of specific brands. We note that the Surgeon General's 2014 report states that "data from the 1997–2011 obtained from the National YRBS indicate that current cigar use among male high school students declined from 1997–2005 and then remained stable from 2005–2011. Among female students, current cigar use declined from 1997–2011." (Ref. 9 at 736, internal references omitted). The 2013 YRBS, a nationally representative survey of 13,000 youths, indicated that cigar use prevalence trends have *decreased* from 1997–2013 for youth in grades 9 through 12 (22 percent in 1997 to 12.6 percent in 2013) (Ref. 29).

Evidence suggests that some youth may recognize the brand of cigar they smoke, but not that it is a "cigar" in general terms and, therefore, may not report their cigar use (Refs. 98, 100). When examples of brand names were added to the 2012 NYTS, there was a pronounced increase from 2011 in reported cigar smoking among non-Hispanic black females (Ref. 100). Among NYTS high school students overall from 2000 to 2011, there was no change in prevalence of cigar smoking (Ref. 101). This lack of decline in cigar smoking is a concern considering cigarette smoking among high school students did significantly decline over these periods (id.). Among NYTS high school students overall from 2011 to 2014, there was a decrease in prevalence of current use of cigars from 11.6 percent to 8.2 percent (Ref. 22).

(Comment 92) The comments were divided as to whether youth use premium cigars. Some comments provided data demonstrating youth use of premium cigars. Others submitted mainly informal industry surveys and anecdotal evidence illustrating that the majority of premium cigar users are older adult males who smoke infrequently and often in a celebratory nature. A few other comments stated that patterns of use studies are inconclusive, because many studies do not differentiate between premium cigars and mass-market cigars.

(Response) Although youth and young adults tend to smoke mass market cigar brands, they are also using premium cigars. In one study, researchers used data from the 2010–2011 NSDUH and Nielsen market scanner data to define a study sample consisting of 6,678 past 30-day cigar smokers who reported smoking a usual brand of cigars (Ref. 59). While many youth identified a mass market cigar as the brand they used most often, this analysis reveals that 3.8 percent of youth aged 12 to 17 and 12.1 percent of young adults aged 18 to 25 also identified certain premium cigars to be the brand they smoked most often (id.). Individuals in both cohorts reported at least eight different premium cigar brands among the brands they used most often, providing evidence that youth and young adults are smoking premium cigars (id.).

One study analyzing data from the 2012–2013 National Adult Tobacco Survey (NATS), with 60,192 participants 18 years and older found that of those smokers whose type of cigar could be identified based on the attributes of their usual product (*e.g.,* premium cigar smoker, little cigar smoker, cigarillo smoker), 19.9 percent were premium cigar smokers (Ref. 90). More specifically, 15.1 percent of cigar smokers aged 18 to 29 years old, who identified themselves as smoking every day, some days, or rarely, indicated the cigar they usually smoked on those occasions was a premium cigar (id.), which clearly illustrates that young adults are using premium cigars. Although some comments questioned the applicability of the NATS data on premium cigar use by youth and young adults (in part, because the study did not use the proposed definition of "premium cigar" in the NPRM), FDA is not persuaded. FDA does not believe it is necessary for the definition of premium cigars in this study to match exactly the definition in the NPRM in order to draw inferences about the use of different types of cigar products. These data, along with the NSDUH and Nielsen market scanner data discussed previously, clearly indicate that youth and young adults are using premium cigars.

Some comments stated the previously mentioned studies show only minimal premium cigar use by minors. By contrast, they relied on Soldz et al. (Ref. 102), which examined preferred cigar brands based on a survey of Massachusetts middle and high school students. Although the study did not include any particular premium cigars among the brands reported, 16.4 percent of youth cigars users were categorized as preferring a "non-listed" brand which the authors suggested "may largely consist of premium cigars." The authors based this determination given the participants' positive association between the "non-listed" brands and parental cigar use and the negative association between the listed cigar brands and parental cigar use. Consequently, FDA does not believe this study demonstrates that youth do not use premium cigars. These comments also did not provide persuasive peer-reviewed evidence indicating that youth and young adults do not use these products. In addition, comments stating that youth and adult cigar use studies are not conclusive with regard to premium cigars because they do not differentiate between cigar types are not persuasive. Such studies show that youth and young adults smoke cigars, and other studies that do differentiate between product types, such as those previously discussed, indicate that youth and young adults do, in fact, use premium cigars.

In light of the health risks associated with the use of all types of cigars, FDA has selected Option 1 and is deeming all cigars, including premium cigars, in this rule.

(Comment 93) A few comments disagreed with FDA's characterization of one study cited in the NPRM (Ref. 103) for the proposition that young adults often mistakenly view non-cigarette tobacco products, such as cigars, as safe alternatives to cigarettes. They noted that most young adult participants in the study rated shisha, herbal cigarettes, and herbal smokeless as "safer than cigarettes," but rated cigars and kreteks as more harmful.

(Response) Many consumers believe that noncigarette tobacco products, including cigars, are less harmful than cigarettes. Although the overall study population did rate cigars as more harmful, there were subgroups (such as African Americans and non-Hispanic whites) that rated cigars from "a little safer" to "much safer." Deeming all tobacco products, including premium cigars, to be subject to chapter IX of the FD&C Act will help to alleviate mistaken beliefs that certain tobacco products are safe alternatives to cigarettes by virtue of the fact that they are not subject to FDA regulation.

(Comment 94) A few comments also stated that premium cigar use among young adults is irrelevant because Congress did not task FDA with protecting young adults who are lawfully permitted to purchase tobacco products.

(Response) FDA is concerned with tobacco use by all age groups, including young adults and adults who may lawfully purchase these products. The Tobacco Control Act charges FDA with protecting the public health generally, not only the health of minors (section 3 of the Tobacco Control Act). Nevertheless, FDA is particularly concerned with tobacco use by youth and young adults, as they are uniquely more susceptible to becoming addicted to nicotine than adults or older smokers. As discussed in the NPRM, most tobacco users begin using prior to the age of 18 and believing they will be able to quit. However, most youth are unable to stop tobacco use once they become addicted. Accordingly, FDA is taking steps to reduce the potential harm to youth and young adults from tobacco products.

(Comment 95) Many comments expressed concerns regarding flavored cigars, including flavored premium cigars, and their effect on youth initiation. Some comments concluded there is no evidence that minors consume flavored premium cigars, relying on one study in which the flavored premium cigar brands of youth use accounted for only a fraction (0.1 percent) of the less than 4 percent reported use of premium cigar brands (Ref. 59).

(Response) FDA is announcing that it intends in the future to issue a proposed product standard that, if finalized, would eliminate characterizing flavors in all cigars including cigarillos and little cigars.

(Comment 96) Some comments argued that premium cigars do not pose youth access issues because manufacturers and retailers do not market them to youth (*i.e.,* they are not cheap, candy- and fruit-flavored, or easy to access) and age verification is already required at the point of sale limiting access to adults only. They relied, in part, on FDA's statements in the 1996 tobacco youth access rule in which FDA stated there was insufficient evidence of youth cigar use to warrant cigar regulation (61 FR 44396). The comments stated there is no evidence that the situation has changed since then and that exempting premium cigars from tobacco product regulation is also warranted because youth do not use premium cigars to any significant degree.

(Response) FDA disagrees. The Agency's statement regarding the availability of evidence to support cigar regulation was made 18 years ago and based on the evidence available at that time. In fact, FDA explicitly stated that there was insufficient evidence to regulate cigars "at this time" (*i.e.,* 1996) (61 FR 44396 at 44422). Moreover, the 1996 rule was issued under the authority of the FD&C Act prior to the passage of the Tobacco Control Act. Consequently, one of the reasons FDA did not assert jurisdiction over cigars in the 1996 rule was because it did not have sufficient evidence "that these products satisfy the definitions of drug and device in the act" (61 FR 44396 at 44423). Cigars, including premium cigars, clearly do satisfy the definition of a "tobacco product" and evidence has become available since 1996 indicating that youth and young adults use cigars, including premium cigars (Refs. 59, 68, 90).

C. Patterns of Use Do Not Preclude Users From Experiencing Negative Health Effects

Proponents of Option 2 claimed that patterns of use preclude premium cigar smokers from experiencing the negative health effects of tobacco smoke because they smoke infrequently and do not inhale. However, despite our explicit requests in the NPRM, the comments did not include data indicating that premium cigar smokers are not subject to disease risk and addiction. FDA's responses to comments regarding these issues are included as follows.

(Comment 97) Many comments stated that a majority of cigar users are occasional smokers (two to six cigars per week) and do not inhale (citing Refs. 69, 75). They also indicated that premium cigar use does not lead to addiction. Finally, some comments noted that occasional cigar users have not been studied in epidemiological research, and data for the lowest level of cigar users (one to two cigars per day) do not reveal mortality rates that are significantly different from nonsmokers (Refs. 69, 79). However, other comments included evidence suggesting increased disease risk and nicotine dependence among infrequent cigar users and those reporting they do not inhale.

(Response) FDA disagrees that patterns of use preclude premium cigar users from experiencing the negative health effects of these products. All cigars produce toxic cigar smoke (Refs. 35, 69). In addition, studies have shown that cigar smoking can cause several different types of cancer even without inhalation (Refs. 69, 104). For example, one study found an increased risk in head and neck cancers in people who were not cigarette smokers but had previously smoked only cigars (Ref. 104).

While inhaling cigar smoke poses much higher morbidity and mortality rates than not inhaling, significant risk still exists for those who do not inhale. Researchers found that the risk of stomach cancer mortality was significantly higher among cigar users who reported they did not inhale when compared to those who did not use tobacco products (Ref. 105). Additionally, among primary cigar smokers reporting that they do not inhale, relative mortality risk was still highly elevated for oral, esophageal, and laryngeal cancers (Ref. 83). A recent systematic review of cigar smoking and mortality summarized the results of 22 published studies from 16 different prospective cohorts and found that primary cigar smoking was associated with increased risk of mortality from all causes, several types of cancers, coronary heart disease, and aortic aneurysm compared to nonsmokers (Ref. 82). Mortality risks were greater with increasing number of cigars smoked per day and self-reported level of inhalation; however, primary cigar smokers reporting no inhalation still had highly elevated mortality risks for oral, esophageal, and laryngeal cancers compared to nonsmokers (id.). In addition, even if they do not intend to inhale and are not aware that they are doing so, most cigar smokers do inhale some amount of smoke (Refs. 32, 34).

Although studies indicate that some cigar smokers may absorb less tobacco smoke, they also show that all cigar smoking is harmful. Regardless of whether cigar smokers inhale, they are still subject to the addictive and other adverse health effects of the product through absorption of nicotine and harmful constituents (Refs. 32, 81).

(Comment 98) Supporters of Option 2 claimed that premium cigar smokers use cigars less frequently than cigarette and smokeless tobacco users and, therefore, premium cigars should either not be regulated or should be subject to less regulation. They relied upon a study showing that the adult prevalence of everyday or occasional use of cigarettes was 18 percent and 2.6 percent for smokeless tobacco products, compared to 2 percent for cigars, cigarillos, and little filtered cigars (Ref. 106).

(Response) Although the prevalence of cigar smoking in the U.S. population is lower than cigarette smoking, use of cigars still presents health risks. Researchers estimate that regular cigar smoking was responsible for approximately 9,000 premature deaths or almost 140,000 years of potential life lost among adults 35 years or older in 2010 (Ref. 68). As stated in the previous response, all cigars produce toxic cigar smoke (Refs. 35, 69). Any cigar use exposes the mouth and throat to tobacco smoke and studies have shown that cigar smoking can cause several different types of cancer even without inhalation (Refs. 69, 104). Health risks still exists for those who do not inhale. For example, researchers found that the risk of stomach cancer mortality was significantly higher among cigar users who reported they did not inhale when compared to those who did not use tobacco products (Ref. 107). Additionally, among primary cigar smokers reporting that they do not inhale, relative mortality risk was still highly elevated for oral, esophageal, and laryngeal cancers (Ref. 83). Therefore, all cigars expose users to toxic and cancer-causing substances and increase the risk of harm. Basing an exemption for premium cigars on current use patterns would be inappropriate given that patterns may change over time and in response to regulation. Consequently, FDA has concluded that deeming all cigars, including premium cigars, is appropriate for the protection of the public health.

D. Responses to Other Cigar Comments

(Comment 99) Some comments expressed concern that if FDA did not deem all tobacco products subject to regulation, the tobacco industry would adjust its products to fit the exemption for premium cigars in Option 2 and preferential economic treatment of certain manufacturers would result. These comments argued that just as manufacturers of roll-your-own tobacco changed their roll-your-own product to classify it as pipe tobacco to take advantage of positive tax treatment, manufacturers would seek similar ways to circumvent regulations and continue marketing products that are detrimental to public health.

(Response) Because FDA has selected Option 1 deeming all cigars, rather than a subset, for this final rule, these comments are moot.

(Comment 100) Many comments stated that it is important for FDA to regulate all tobacco products, including cigars, pipe tobacco, and e-cigarettes in the same way, and that the Agency should ensure that a consistent set of regulatory criteria is applied to all tobacco products and nicotine delivery systems. According to the comments, failure to regulate all tobacco products would provide incentives for manufacturers to market new tobacco-based or tobacco-derived products that are unregulated and may induce people to switch to the unregulated products.

(Response) FDA agrees that it is appropriate for the protection of the public health to regulate all tobacco-derived products meeting the definition of "tobacco product." There is inherent risk in all tobacco-derived products. Further, the Agency agrees that use patterns may change (and have changed) over time and in response to regulation.

(Comment 101) At least one comment expressed concern that FDA relied upon an abstract presented at the Conference for the Society for Research on Nicotine and Tobacco (SRNT) as a basis for proposing Option 1. The comment stated that because the abstract was not a full peer-reviewed research article, stakeholders were unable to adequately respond to the claims made.

(Response) FDA disagrees. Additional analysis of the data that was the subject of this SRNT abstract was conducted and a paper was published and submitted to the docket, allowing for stakeholders to comment on it (Ref. 90). The abstract presented at SRNT also was not the sole basis for proposing Option 1. FDA appropriately characterized this as preliminary data and included additional data and information to support this proposed option. In addition, FDA has supplemented the information and data supporting Option 1, as discussed in section VII, to provide additional evidence of premium cigar use by youth and young adults and to illustrate that the patterns of use for premium cigars do not preclude users from negative health effects.

(Comment 102) Comments urged FDA to adopt a category-specific approach to regulation of cigars in order to more effectively address the variations in use patterns, manufacturing, and ingredients across the product category. Other comments, however, urged FDA to broadly regulate all cigars in the same way to reduce initiation and current use among youth. More specifically, comments advocated prohibiting flavors, including menthol, in all cigars, prohibiting self-service displays, and establishing minimum pack size requirements for all cigars.

(Response) Although the statute does not require FDA to make any public health finding in order to deem tobacco products, the Agency has determined that cigar use presents health risks and that all cigars should be brought under its regulatory authority. However, FDA is providing a compliance policy that will provide additional time for manufacturers of newly deemed products to comply with certain requirements, and which will reduce the burdens on manufacturers as they become regulated by FDA for the first time. As explained elsewhere in this document, FDA is announcing that it intends in the future to issue a proposed product standard that would eliminate characterizing flavors in all cigars including cigarillos and little cigars.

(Comment 103) Some comments supporting Option 2 argued that FDA is not obligated to deem all tobacco products that meet the statutory definition of "tobacco product." They also stated that the intent of the Tobacco Control Act was to target tobacco products marketed to children and products that cause addiction, which is why "cigarette" and "little cigar" were specifically defined in the Tobacco Control Act and large and premium cigars were not similarly defined. Thus, they claim exempting premium cigars is consistent with Congress' intent that premium cigars not be regulated, which they state is further evidenced by introduction of such legislation in Congress.

(Response) FDA agrees that the Agency is not obligated to deem all tobacco products but disagrees with comments purporting to explain Congress' intent to only regulate products marketed to children. The purpose of the Tobacco Control Act was to provide authority to FDA to regulate tobacco products and protect not only the health of minors, but also the health of the public overall (section 3 of the Tobacco Control Act). While use of tobacco products by youth was and continues to be a significant focus of the law, it is clear that Congress did not intend that the Tobacco Control Act reach only products marketed to children, as they included many provisions applicable to tobacco products marketed to adults.

(Comment 104) Many comments expressed concern that premium cigar regulation would impose considerable costs and place excessive burdens on small businesses without quantifiable benefits. In particular, many comments stated that premarket review would be cost-prohibitive for premium cigar manufacturers, effectively eliminating their ability to release special editions and seasonal blends. They also claimed that HPHC testing and reporting and other regulatory requirements like the prohibition on free samples would be equivalent to a de facto ban on premium cigars. They also expressed concern about the political and economic impact of premium cigar regulation on two foreign nations given the potential impact on production and exports of their premium cigars to the United States.

Some comments also argued that an exemption for premium cigars is appropriate, because premium cigars are unique in the way that they are made, marketed, sold, purchased, and used. They stated that regulation would stifle innovation in the premium cigar market, devastate a long-time social and cultural phenomenon, and limit the freedoms of businesses and consenting adults to sell and purchase a legal product.

(Response) FDA understands these concerns. The Agency has determined that cigar use presents health risks and that all cigars should be brought under its regulatory authority.

To assist newly regulated firms, FDA is announcing in this final rule a compliance policy to address some of the possible burdens suggested by comments (section IV.D). For example, FDA does not intend to enforce the premarket review requirements against cigar manufacturers that make tobacco blending changes to address the natural variation of tobacco (*e.g.,* tobacco blending changes due to variation in growing conditions) in order to maintain a consistent product. However, FDA intends to enforce the premarket requirements for products that have tobacco blending changes (including those involved in seasonal and boutique blends) that are intended to alter chemical or perception properties of the new tobacco product (*e.g.,* nicotine level, pH, smoothness, harshness). FDA also is working to determine an appropriate compliance policy to deal with HPHCs for newly deemed products and is intending to issue guidance regarding HPHC reporting, and later a testing and reporting regulation as required by section 915, with enough time for manufacturers to report given the 3-year HPHC reporting compliance period. As noted elsewhere in this document, FDA does not intend to enforce the reporting requirements for newly deemed products before the close of the 3-year compliance period, even if the guidance is issued well in advance of that time. In addition, as discussed in section IV.D, FDA is announcing a compliance policy for small-scale tobacco product manufacturers (which likely would include premium cigar manufacturers), which states that FDA generally intends to grant small-scale tobacco manufacturers additional time to respond to SE deficiency letters and to not bring enforcement action against those small-scale tobacco product manufacturers who submit ingredient lists within 12 months of the effective date of the rule, and is granting these manufacturers an additional six-month compliance period for the requirements to submit tobacco health documents. FDA believes that this compliance policy will help to assist these manufacturers with regulatory compliance.

FDA also understands concerns from cigar retailers about the effect that a ban on free samples could have on their ability to promote new products. FDA wishes to clarify that allowing prospective adult buyers to smell or handle a cigar is not considered the distribution of a "free sample" for the purpose of 21 CFR 1140.16 as long as the product is not actually consumed in the retail facility and the prospective buyer does not leave the facility with a free tobacco product (whole or part). Affording adult consumers the opportunity to handle the product will give them the ability to feel the resistance of the cigar's structure, and allow them to clearly see the color of the product, which is an indication of the fermentation period for the tobacco. It also will allow users to capture the aroma of the cigar and the box (if the cigar is sold in a package). Therefore, it would not be considered a free sample if a prospective buyer smells the cigar while handling it. We believe that in most circumstances, other retail facilities, including ENDS retail establishments, can similarly allow customers to touch, hold, and smell their products without violating the free sample ban. However, if the prospective buyer lights and draws or puffs on the cigar to keep the cigar lit, or otherwise uses the free cigar or leaves the retail establishment with a free cigar, this would constitute a "free sample" in violation of § 1140.16.

(Comment 105) Many comments requested that the exemption for premium cigars be extended to hand-operated, vintage machine-made cigars. Comments stated such cigars are indistinguishable from handmade premium cigars, are sold on the same shelves as premium cigars, and do not resemble mass-market cigars. The comments further argued that consumers perceive them to be just like value-priced handmade cigars and treating them differently would create significant enforcement issues for FDA. They stated that, without an exemption, manufacturers of these products would be forced to close and eliminate jobs, negatively impacting the regional economy where such cigars are produced.

(Response) As already stated, FDA has selected Option 1 deeming all cigars, rather than a subset, for this final deeming rule. Therefore, all cigars, including hand-operated, vintage machine-made cigars, are deemed and subject to the requirements of chapter IX of the FD&C Act and implementing regulations. Concerns noted by some comments about the burdens of regulation are addressed in sections IV.C and IV.D.

(Comment 106) At least one comment expressed concern that retailers may not be able to determine whether a cigar meets all of the elements of the final definition of a "covered cigar." Therefore, the comment stated that retailers should not be liable for a manufacturer's improperly labeled premium cigars (similar to the retailer "safe harbor" for required warning labels and advertising in the proposed cigarette graphic warning rule (75 FR 69524 at 69535, November 12, 2010)).

(Response) FDA has selected Option 1, which requires all cigars (rather than a subset) to include the textual health warnings. FDA also notes, however, that § 1143.5(a)(4) does provide a retailer "safe harbor" for required warning labels for packaging that contains a health warning; is supplied to the retailer by a manufacturer, importer, or distributor who has the required state, local, or Alcohol and Tobacco Tax and Trade Bureau (TTB)-issued license or permit, if applicable; and is not altered by the retailer in a way that is material to the requirements of § 1143.5. Retailers must have the required warnings on advertisements as stated in § 1143.5(b)(1).

(Comment 107) Some comments stated that FDA has the authority to assert jurisdiction over all cigars and differentially apply regulations to certain cigars if shown to be appropriate based on scientific evidence. Thus, according to the comments, if it were established that premium cigar risk is of a different nature and degree than the risks of other types of cigars based on who uses them and how they are used, the Agency could apply its authority in a way that fits the risks posed by the product. These comments concluded that because of this, it is unnecessary and would be inappropriate to completely exempt premium cigars.

Similarly, some comments applied the notion of a "continuum of risk" to cigars. They stated that premium cigars are at the lower end of the spectrum (Ref. 76) due to the common usage patterns (*i.e.,* described as most frequently used by adults, on special occasions, and users do not inhale). Therefore, they urged that FDA regulate premium cigars in line with the notion of a continuum of risk.

(Response) FDA agrees that a continuum of nicotine-delivering products does exist as demonstrated by the lower levels of toxicants in ENDS in comparison to cigarettes, and may warrant different requirements for products at different ends of this continuum. However, commenters have not substantiated their claims that the patterns of use for premium cigars preclude users from negative health effects. Instead, as discussed throughout this section, cigar use poses a greater risk than not smoking, and lack of inhalation do not prevent the onset of cigar-related morbidity and mortality. Therefore, FDA has concluded that it is appropriate for all cigars to be brought under its regulatory authority.

(Comment 108) Several comments stated that it would be inappropriate and inaccurate for FDA to treat "cigars" as a single homogenous category or to simply overlay the existing regulatory framework for cigarettes onto the diverse suite of deemed products. They further stated that because of the significant differences among cigar products, it is critical that FDA distinguish between the specific cigar subtypes in determining whether any, some, or all cigars should be subject to regulation. If FDA were to do otherwise, they believe the Agency would risk establishing an arbitrary and capricious, overly broad regulatory scheme that fails to meet its burden to protect the public health without imposing undue burden on the industry.

(Response) FDA disagrees. Upon review of comments and scientific evidence, FDA has determined that all cigars present a risk to public health and, consequently, should be deemed.

(Comment 109) A few comments discussed different regulatory approaches for make-your-own cigar products (*e.g.,* cigar wrappers and cigar tobacco). At least one comment suggested treating these products as cigars while others urged regulation of them in a manner similar to cigarette papers and roll-your-own tobacco.

(Response) With this final rule, make-your-own cigar products, including cigar wrappers and cigar tobacco, are tobacco products and subject to FDA's tobacco control authorities under chapter IX of the FD&C Act. Cigar wrappers containing tobacco or tobacco-derived nicotine and cigar tobacco packaged and sold individually are also subject to the warning requirement for "covered tobacco products" found in § 1143.3.

(Comment 110) At least one comment stated that FDA should not permit manufacturers to self-classify their products as cigarettes or cigars, and if premium cigars are exempted, should not permit self-classification of cigars as premium or nonpremium.

(Response) Regardless of how they may be classified by their manufacturers, cigars and cigarettes will be classified based on the definitions included in this final rule.

(Comment 111) A few comments argued that bias existed for any study or analysis cited in the NPRM that was written or contributed to by FDA employees. These comments were concerned that FDA employees generating and analyzing data did so to support the proposed regulation of cigars.

(Response) FDA disagrees. FDA notes that most of the studies cited in the NPRM that were authored by FDA employees have been published in peer-reviewed journals. Where the NPRM discussed research results presented at a professional conference, SRNT, but not yet included in a peer-reviewed journal, FDA clearly stated so and specifically requested comment (79 FR at 23151). That research has since been published (Ref. 90).

(Comment 112) Some comments criticized the methodologies used by researchers in studies FDA cited in the NPRM (*e.g.,* Ref. 59). For example, they claimed that the Delnevo, et al. study regarding youth use of flavored cigars (id.) was flawed, because the study cites any use of the brand by youth as use of the flavored variety of that cigar brand (even though the respondent might use an unflavored variety of that cigar). The comments had additional concerns regarding the study, such as missing data on cigar brand from 13 percent of cigar smokers, as well as concerns about whether study participants provided accurate information regarding cigar brand used, and whether the study population was representative of the U.S. population. Other comments stated that studies in peer-review journals are politically biased and that studies that oppose tobacco product regulation are often prohibited from publication.

(Response) The Delnevo, et al. publication found that youth and young adults are significantly more likely than older adults to prefer cigar brands that are more likely to be flavored (Ref. 59). Because no national data directly compared youth and adult flavored cigar use within the same study, Delnevo and colleagues conducted an ecological analysis combining data from the 2010–2011 NSDUH on cigar brand smoked most often, with Nielsen data indicating the percent of the cigar brands' market share that are labeled as flavored cigar products. These results, coupled with information on the prevalence of flavored cigar use from studies restricted to youth or to young adults, provide additional indirect evidence of the popularity of flavored cigars among younger cigar smokers as compared to older adult cigar smokers. Especially when coupled with research results on the prevalence of flavored cigar use in studies restricted to youth or young adults, this study provides additional supporting evidence of the widespread appeal of flavored varieties of these products among young Americans. The comments noted that, in the 2010–11 NSDUH, 13 percent of cigar smokers did not report a usual cigar brand and expressed concern about the ability of those who reported their usual cigar brands to do so accurately. Some cigar smokers may in fact not actually have a cigar brand they smoke most often and consequently did not provide a brand response, while other respondents may have chosen not to provide their usual brand information. Among the latter group, missing data is always a concern, although there is no evidence from the study to suggest that those who provided brand information were systematically different than those who did not. Additionally, the comments did not provide evidence to substantiate the concern that respondents were not reporting the brand names they actually used. Lastly, FDA does not agree with concerns about representativeness of the survey. The NSDUH is designed to be representative of the U.S. civilian, non-institutionalized population, ages 12 and older (*http://www.samhsa.gov/data/population-data-nsduh*). FDA does not rely on any single study to support decisions included in this final rule. FDA cited many peer reviewed studies in the NPRM and relies upon many peer-reviewed studies to support the decisions included in this final rule, including the Delnevo publication.

VIII. Regulation of Electronic Nicotine Delivery Systems (Including E-Cigarettes) and the Continuum of Nicotine-Delivering Products

In the preamble to the NPRM, FDA noted that there are distinctions in the health risks presented by various nicotine-delivering products. FDA requested comment as to how e-cigarettes should be regulated based on this continuum of risk. We explained that some studies have revealed the existence of toxicants in both the e-cigarette liquid and the exhaled aerosol of some e-cigarettes but that we do not have sufficient data to determine what effects e-cigarettes have on public health at the population level. We also noted that some individuals report using e-cigarettes to successfully quit smoking, but we expressed concerns about dual use of e-cigarettes and combusted tobacco products and the possibility that flavored e-liquids are leading children to initiate tobacco use with e-cigarettes.

In this final rule, FDA clarifies that although there are many types of ENDS (including e-cigarettes, e-cigars, e-hookah, vape pens, personal vaporizers, and electronic pipes), all are subject to FDA's chapter IX authorities with this final deeming rule. Comments regarding e-cigarettes, including comments on how the products should be regulated in light of this continuum, and FDA's responses are discussed in the following sections.

A. Terminology

(Comment 113) Some comments expressed confusion as to what is encompassed by the term "e-cigarette." Other comments stated that the "electronic smoking devices" covered under this deeming rule should include e-cigarettes, e-cigars, e-hookah, and vape pens.

(Response) FDA agrees that electronic nicotine delivery systems or ENDS are sold under several different names including e-cigarettes, e-cigars, e-hookah, vape pens, personal vaporizers, and electronic pipes. These products all meet the definition of "tobacco product" and, therefore, under this rule, all are subject to FDA's tobacco control authorities, regardless of a novel name or heating source. In addition, the definition of tobacco product includes components and parts (the objects intended or reasonably expected to be used with or for the human consumption of a tobacco product that are not accessories) (*e.g.,* e-liquids, tanks, cartridges, pods, wicks, atomizers), which, under this rule, have also been deemed to be subject to FDA's authority under chapter IX of the FD&C Act.

B. Prevalence

In the NPRM, FDA expressed concern about the increase in prevalence of the newly deemed products, particularly the alarming rise in e-cigarette use by middle school and high school students. The comments included peer-review studies, focus group results, and data regarding the prevalence of ENDS use.

(Comment 114) Some comments noted that it was difficult to fully ascertain prevalence of use of these products because they are sold under many different names. However, they generally agreed that the prevalence of e-cigarette use has increased in recent years, citing peer-reviewed studies and data from state or regional surveys (*e.g.,* Ref. 108). For example, comments cited the 2013 North Carolina Youth Tobacco Survey (NCYTS) and expressed concern that, while the current cigarette smoking rates among North Carolina high school students decreased in recent years, the overall current use of tobacco products increased from 22.5 percent in 2011 to 24.5 percent in 2013. In particular, the rate of e-cigarette use increased from 1.7 percent in 2011 to 7.7 percent in 2013, and 2.7 percent of high school students who had never tried a cigarette indicated that they were considering using e-cigarettes in the next year.

However, some of these comments believed that the data showing an increase in e-cigarette use among youth and young adults only reflects their experimentation (and not long-term use) and that there are no data showing that this experimentation leads to long-term use or dual use with combusted tobacco products. Others stated that although e-cigarette use may be increasing among youth and young adults, this increase is due to the fact that young adult smokers are switching to e-cigarettes, as are adult smokers.

(Response) FDA agrees with comments stating that the prevalence of use of the newly deemed tobacco products has been increasing, which further substantiates the need for this final rule. FDA remains concerned about the rise in use of newly deemed products by youth and young adults, particularly the increase in use of ENDS. As we stated in the NPRM and throughout this document, long-term studies are not yet available to determine whether these youth and young adults are only experimenting with tobacco use, becoming established ENDS users or dual users, or transitioning to combusted products. In addition, there is not sufficient evidence to conclude that youth and young adults are using ENDS as a means to quit smoking.

(Comment 115) Many comments contended that the great majority of e-cigarette users consist of former smokers and those trying to quit smoking, rather than those who are initiating tobacco use with e-cigarettes (*e.g.,* Ref. 109). The comments included data from regional surveys indicating that even where there has been a significant increase in youth and young adult e-cigarette use, the increase is seen in experimenters and not daily users. For example, a few comments referred to a report commissioned by Public Health England which referred to a study that found that only 1 percent of 16 to 18-year-old never smokers have experimented with e-cigarettes and few, if any, progress to sustained use (Ref. 110).

(Response) Data reported by the CDC's National Center for Health Statistics (NCHS), which provides the first estimates of e-cigarette use among U.S. adults from a nationally representative household interview study, indicate that current cigarette smokers and recent former smokers (*i.e.,* those individuals who quit smoking within the past year) were more likely to use e-cigarettes than long-term former smokers (*i.e.,* those individuals who quit smoking more than one year ago) and adults who had never smoked (Ref. 24). In addition, the CDC states that current cigarette smokers who had tried to quit smoking in the past year were more likely to use e-cigarettes than those who had not tried to quit (id.). It is noted that it cannot be determined by the research findings: (1) Whether former cigarette smokers who now exclusively use e-cigarettes would have ceased smoking cigarettes regardless of e-cigarette use; and (2) whether the e-cigarette use preceded or followed smoking cessation. Similar patterns have been observed in Europe, where researchers found that "e-cigarette use was more likely among smokers who had made a past year quit attempt" when compared to smokers who had not (Ref. 111). As discussed in further detail in response to Comment 144, a meta-analysis of 15 cohort studies, 3 cross-sectional studies, and two clinical trials (one RCT, one non-RCT) found that cigarette smokers who also used e-cigarettes had statistically significantly worse quit rates than those cigarette smokers who did not use e-cigarettes (Ref. 112).

However, FDA also remains concerned about the dramatic rise in ENDS use among youth; between 2011 and 2014, past 30 day e-cigarette use among high school students increased nearly 800 percent from 1.5 percent in 2011 to 13.4 percent in 2014 (Ref. 22), and between 2011 and 2013, the number of never-smoking youth who had reported ever using an e-cigarette increased 3-fold, from 79,000 to more than 263,000 youth (Ref. 113). The Surgeon General has stated that adolescents appear to be particularly vulnerable to the adverse effects of nicotine on the central nervous system (Ref. 9), and ENDS may deliver as much nicotine as other tobacco products (Ref. 114).

FDA is investing in long-term, population-level research, such as the PATH Study, to help assess the likelihood that previous nonusers of tobacco who experiment with ENDS will initiate regular tobacco use over time. Such longitudinal studies can further assess the factors associated with potential smoking cessation among e-cigarette users.

(Comment 116) The comments generally agreed that youth are increasingly using e-cigarettes, but disagreed as to the product's impact on nicotine addiction. As FDA noted in the proposal and as discussed by many comments, the CDC found that ever use of e-cigarettes by middle and high school students in the United States increased from 3.3 percent in 2011 to 6.8 percent in 2012 (Ref. 108). While the majority of comments recognized an increase in dual use, some suggested that this was not an issue because youth are using e-cigarettes to quit smoking, resulting in some dual use until they can completely abstain from conventional cigarettes (Ref. 115).

(Response) FDA remains concerned about the rise in ENDS use among youth and young adults as well as the trends in dual use of ENDS and combusted products in both youth and adults (Ref. 116). In addition, as stated in the NPRM and throughout this final rule, all tobacco products are potentially addictive and some ENDS may deliver as much nicotine as other tobacco products (Ref. 20). The Surgeon General has stated that adolescents appear to be particularly vulnerable to the adverse effects of nicotine on the central nervous system (Ref. 9). FDA believes that this final deeming rule, along with the minimum age restrictions and health warning requirements, is an important step toward combatting this rise in tobacco product use among youth and young adults.

A recently published paper by Friedman (Ref. 42) looked at youth smoking rates in states that enacted early bans on sales of e-cigarettes to minors and concluded, based on state-level data available through 2013, that the decline in adolescent smoking rates slowed in states that enacted restrictions on access to ENDS by minors before January 2013, relative to states that did not. Given the various issues with this study (see previous discussion regarding this publication in response to comment 33), FDA acknowledges this paper as a first attempt to study potential impacts of youth ENDS access restrictions, but emphasizes that further research will be needed to explore the effects of this rule on product switching and dual usage.

C. Toxicity and Nicotine in E-Liquid and Aerosol

Although FDA noted in the NPRM that we do not currently have sufficient data about e-cigarettes and similar products to fully determine what effects they have on the public health, we identified concerns regarding the toxicants in e-liquid and the exhaled aerosol and the nicotine delivery from e-cigarettes. Comments were divided on the safety and toxicity of e-liquids, e-cigarettes, and the exhaled aerosol.

(Comment 117) The comments expressed concerns that e-cigarette users subject themselves to dangerous constituents, including formaldehyde and other toxicants. One comment stated that the release of formaldehyde occurs only when the voltage on e-cigarettes is set to 4.8 volts or higher (Ref. 67). Some comments also submitted studies showing the existence of other e-liquid constituents, including prescription weight loss and erectile dysfunction drugs (Ref. 117).

(Response) Studies show that e-liquid tobacco products contain nicotine, propylene glycol, glycerin, tobacco specific nitrosamines, tobacco alkaloids, carbonyls, ethylene glycol, diacetyl, and acetyl propionyl (Refs. 19, 118, 119). Chemicals such as nicotine, carbonyls, tobacco specific nitrosamines, heavy metals, and volatile organic compounds have been identified in e-cigarette aerosols (Refs. 19, 118, 119, 120, 121, 122).

In addition, several studies substantiated the data included with comments, finding that flavored e-liquids contain chemicals that could be dangerous to consumers when inhaled. For example, researchers in one study tested 159 e-liquids with sweet flavors, such as toffee, chocolate, and caramel, and found that almost three quarters of the samples (74 percent) contained diacetyl or acetyl propionyl (Ref. 123), both of which pose known inhalation risks (*e.g.*, Ref. 124). Among those that tested positive, nearly half of the e-liquids in the study could expose users to levels that exceed recommended workplace limits for breathing these chemicals (Ref. 123). An additional recent study analyzed 51 types of flavored e-cigarettes for total mass of diacetyl, 2,3-pentanedione, and acetoin (Ref. 125). Researchers detected diacetyl above the laboratory limit of detection 39 of the 51 flavors tested, ranging from limit of qualification (LOQ) to 239 μg/e-cigarette. 2,3-pentanedione and acetoin were also detected in 23 and 46 of the 51 flavors tested at concentrations up to 64 and 529 μg/e-cigarette (id.). It is noted that the study involved a convenience sample of 51 types of flavored e-cigarettes and may not be representative of the types of e-liquids currently available to users. Absent a regulatory standard, FDA acknowledges that it may not be possible to account for the wide variability of concentrations of constituents in the flavors of current ENDS products. Another study analyzed 30 e-cigarette liquids and found that many flavors, including cotton candy and bubble gum, contained aldehydes, a class of chemicals that can cause respiratory irritation, airway constriction, and other effects (Ref. 126). Specifically, researchers noted that two flavors, a dark chocolate and a wild cherry, would expose e-cigarette users to more than twice the recommended workplace safety limit for the aldehydes vanillin and benzaldehyde (id.). Similarly, researchers found that several cinnamon-flavored e-liquids contained a chemical, cinnamaldehyde, which researchers stated was highly toxic to human cells in laboratory tests (Ref. 127).

Some studies have found that lower levels of toxicants are observed in e-cigarette aerosols than in combusted tobacco smoke (Ref. 122). FDA recognizes that specific product design parameters, such as voltage, can affect toxicant deliveries (Ref. 67). For example, some ENDS devices and some power levels of operating ENDS devices have been reported to deliver more formaldehyde than other ENDS products and conventional cigarettes (Refs. 67, 128, 129) and can affect the public health. In addition, a 2010 study conducted by the Virginia Commonwealth University determined that in a controlled evaluation of smokers naïve to the use of e-cigarettes and using a particular model of e-cigarette, acute effects of using the product did not result in measurable levels of nicotine or carbon monoxide, although e-cigarettes did suppress nicotine/tobacco abstinence symptom ratings (Ref. 130). Moreover, a recent evaluation of the relative health risks of ENDS products conducted by Public Health England has drawn attention to scientific reviews concluding that ENDS are "likely to be much less, if at all, harmful to users or bystanders" and a prior paper that reported the findings from an international expert panel of academics. Employing an analysis model that quantifies the relative health harms of 12 tobacco products using a series of 14 harm criteria, the expert panel determined that while cigarettes scored 100 percent in their assessment of maximum relative harm, ENDS products were rated to have only 4 percent maximum relative harm, which contributed to Public Health England's assessment that ENDS are around 95 percent safer than smoking combusted cigarettes (Ref. 131; see Refs. 76, 132).

The recent evaluation's use of the prior paper has several limitations, and the prior paper itself observed that it was reporting outcomes based on the decision-conferencing process from a group of experts who were selected without any "formal criterion," though "care was taken to have raters from many different disciplines" and primarily based on geographic location "to ensure a diversity of expertise and perspective" (Ref. 76). In addition, the authors acknowledge that there is a "lack of hard evidence for the harms of most products on most of the criteria" (Refs. 76, 133, 134). The authors did not explain what scientific information was available to the experts upon which they should base their ratings. The authors did not explain the derivation of the quantitative assessment of each harm criterion. It is unclear if the authors carried out or referenced a quantitative risk analysis, a standard practice when assessing relative risk, nor did the authors indicate that they used mean levels of exposure to HPHCs in users or other quantitative evidence as an approximation of risk. In addition, population effects appear to be largely outside the scope of this analysis since the manuscript did not address the likelihood that the characteristics of the products would make them more or less likely to appeal to new users, be used in conjunction with other tobacco products or discourage quitting. They did not describe an assessment of population effects such as a quantitative assessment of youth use prevalence. FDA does not find the beliefs reported in the prior paper (Ref. 76) to be sufficiently conclusive on the relative risks of using different tobacco products.[14] However, previous studies detected the presence of aldehydes, especially formaldehyde, in the vapor from some ENDS to exist at levels much lower than in cigarette smoke (Ref. 132). Moreover, across several Japanese brands evaluated by another researcher in a self-published Web site, under some use conditions, ENDS released 1/50th of the level of formaldehyde released by cigarettes (Ref. 135). The highest level detected was six times lower than the level in cigarette smoke (id.). A clinical investigation comparing the levels of toxicants and carcinogen metabolites in the urine of e-cigarette users and combusted cigarette users found that e-cigarette users had significantly lower levels of all evaluated toxicants, which included acrolein and crotonaldehyde (Ref. 136). But other research, published as a letter to the editor of the *New England Journal of Medicine*, reported that ENDS devices operated at 5 volts delivered a mean of 390+/−90 µg per 10 puff sample which is greater than 150 µg, the estimated average delivery of formaldehyde than conventional cigarettes. No formaldehyde-releasing agents were detected when ENDS were operated at 3.3 volts (Ref. 128). A subsequent peer-reviewed article on 5 variable-power ENDS devices found large variations in formaldehyde delivery across devices (Ref. 129). The first device yielded more formaldehyde than combustible cigarettes at every power level tested, and the second device delivered more formaldehyde at the highest power level tested; the remaining three devices delivered less formaldehyde than combustible cigarettes at all power levels tested (*id.*) The same research found that aldehyde delivery varied by 750-fold from one ENDS device to another (*id.*). The article referenced in one comment (Ref. 67) reported that increasing the voltage from 3.2 to 4.8 volts increased formaldehyde, acetaldehyde, and acetone levels from 4-fold to over 200-fold.

(Comment 118) The comments in support of limited or no regulation for e-cigarettes cited studies showing that e-cigarette use resulted in improvements in many health indicators of former cigarette smokers. Most of these comments relied upon published literature concluding that, despite the lack of long-term health data, e-cigarettes are "likely to be much less, if at all, harmful to users and bystanders" (Ref. 132). They also noted that clinical studies to date indicate that e-cigarettes generally are well-tolerated and do not produce serious adverse events following use for up to 24 months (Refs. 107, 137). Many relied upon an analysis of the 47 e-cigarette adverse event reports FDA received from 2007 to 2012, which found that only 8 of them were considered serious (*e.g.,* pneumonia, congestive heart failure, disorientation, seizure, hypotension, facial burns, chest pain and rapid heartbeat, infant choking on an e-cigarette cartridge, loss of vision) (Ref. 138).

Some comments also stated that e-cigarettes provide subjective health benefits to current smokers. For example, in one Internet survey of 1,347 current e-cigarette users, among those who were former smokers, 75 percent reported improved breathing, less coughing, and feeling healthier overall after switching to e-cigarettes (Ref. 139). They also claimed that e-cigarette use leads to improved sense of smell and taste and general physical status (Ref. 109). In addition, they stated that some of the harms caused by smoking can be reversed by switching to e-cigarettes (Ref. 140).

(Response) FDA agrees that the majority of reported adverse events appear to have been not serious. The FDA adverse event reporting system has inherent limitations as a measure of the impact of e-cigarettes since ENDS are a newly deemed product and reporting adverse events associated with tobacco products (including e-cigarettes and other ENDS) is voluntary; therefore, the reports received may have underrepresented the true number and types of adverse events associated with ENDS. The data cannot be used to calculate incidence (occurrence) rates or to estimate risk. Moreover, FDA has concerns with relying upon the types of short-term studies provided in the comments. Short-term studies fail to analyze the exposure risk of tobacco use and inhalation that damage health over a lifetime of repeated, extended exposure. Given the relatively new entrance of ENDS on the market, consumers have not had the duration of use for researchers to fully assess the morbidity and mortality effects for ENDS on either the individual or the population.

FDA recognizes that completely switching from combusted cigarettes to ENDS may reduce the risk of tobacco-related disease for individuals currently using combusted tobacco products, given the products' comparative placements on the continuum of nicotine-delivering products. A recent review from Public Health England (discussed in greater detail in response to Comment 117) suggests substantial reductions in the exposure to harmful constituents typically associated with smoking in ENDS products compared to cigarettes, and that most of the chemicals causing smoking-related disease from combusted tobacco use are absent and the chemicals that are present pose limited danger (Ref. 131). A scientific review of published studies of the toxicity of certain e-liquids found that "[e-cigarette] aerosol can contain some of the toxicants present in tobacco smoke, but at levels which are much lower. Long-term health effects of [e-cigarette] use are unknown but compared with cigarettes, [e-cigarettes] are likely to be much less, if at all, harmful to users or bystanders" (Ref. 132). ENDS products have been found in some studies to release aldehydes at much lower levels than that in cigarette smoke, with one Web site posting stating that, across several Japanese brands, under some use conditions, that ENDS products release 1/50th the level of formaldehyde released in cigarettes (Ref. 133).

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[14] In addition, at least one source has identified other flaws with the expert panel employed in the Nutt et al. report, including potential conflicts of interest and no prespecified expertise on tobacco control among the panel members (Ref. 133).

However, study results have been inconsistent about the effects of these products. Some short-term studies suggest that ENDs may not affect heart rate, cardiac function, lung function, or complete blood count indices to the extent of conventional cigarettes (Refs. 130, 141, 142). A literature search, however, concluded that the current scientific evidence on short-term effects are limited and there are no adequate data on long-term health effects (Ref. 143). Other studies have demonstrated increase in mean heart rate and inflammatory measures (such as white blood cells) and changes in lung function after use (Refs. 141, 142, 144, 145). Some research has found that there are some ENDS devices and some power levels of operating ENDS devices that deliver more formaldehyde than other ENDS products and conventional cigarettes (Refs. 67, 128, 129). Further, the review by Hajek et al. (Ref. 132) referred to in this comment as showing health benefits and finding a lack of negative health effects of e-cigarettes, may have limited generalizability due to the variability of e-cigarette products. The authors expressly recognized that there are many deficiencies in the available data.

(Comment 119) Some comments believed that FDA should not be concerned about e-liquids because they are restricted to the same nicotine levels as other products (*e.g.*, cigarettes, hookah, smokeless tobacco, NRTs).

(Response) FDA disagrees with comments stating that the Agency should not be concerned with ENDS use. First, a direct comparison of the nicotine level in cigarettes (and other currently regulated tobacco products) with the nicotine level in e-liquids is not a particularly helpful or relevant comparison. More helpful and clinically meaningful is the comparison between the amount of nicotine delivered to the user after using a cigarette (or other conventional tobacco product) versus the amount of nicotine delivered after using an ENDS (Ref. 146). Therefore, even if an e-liquid has the same nicotine level, it may deliver a different level of nicotine than the comparator product. It is also possible that comparable nicotine delivery consistently produced by ENDS that meet the requirements of the Tobacco Control Act may increase the facilitation of product switching from cigarettes to ENDS—which could (with appropriate regulatory oversight) potentially reduce the overall health harm caused by combusted tobacco. Further research is necessary to determine the causal factors that influence product switching from cigarettes to ENDS (or vice versa) and the subsequent health impacts.

Second, FDA disagrees with the notion that e-liquids are restricted to the same level of nicotine as other tobacco products. E-liquids are available in a wide range of nicotine concentrations, but delivery to the user is based on multiple factors, including the humectant in the e-liquid, the temperature to which the e-liquid is heated, the user experience, device designs, and design modifications (Ref. 147). Data suggest that experienced ENDS users are able to achieve clinically significant nicotine levels and levels similar to those generated by traditional cigarettes (Refs. 114, 148, 149, 150). Moreover, heating the e-liquids to higher temperatures and using the ENDS in ways other than intended (*e.g.*, dripping the e-liquid directly onto the atomizer) may result in nicotine delivery that is actually higher than that of a conventional cigarette (Ref. 16).

Third, FDA disagrees with the premise that the Agency should not be concerned with tobacco products that may have lower nicotine levels than cigarettes or other tobacco products, as may be the case with some ENDS. Even if ENDS products have lower levels of nicotine, they still have the potential to addict users, particularly youth and young adults, as discussed in section VIII.C. As the Surgeon General has stated, nicotine is the primary addictive substance in tobacco products (Ref. 9). Regardless of the nicotine content of the tobacco products, FDA believes that deeming tobacco products will result in significant public health benefits and that the additional restrictions imposed by this rule are appropriate for the protection of the public health.

(Comment 120) One comment expressed concern about the lack of research regarding the environmental impacts of e-cigarette use and storage.

(Response) FDA is funding studies regarding environmental impacts due to ENDS manufacturing, use, and disposal following use. In addition, FDA has been conducting a series of public workshops to obtain information on e-cigarettes and their impact on public health. Potential environmental impacts were discussed during the first workshop (79 FR 55815, September 17, 2014).

(Comment 121) Some comments expressed concern about the health effects of propylene glycol exposure from e-cigarette use. They also stated that the use of glycerol and propylene glycol, both of which are humectants, may cause uninformed users to become inadvertently dehydrated.

(Response) FDA recognizes that information about the health effects of the constituents in e-liquids and ENDS aerosols in both users and nonusers is limited and that this issue should be explored to better understand the impacts of these products on the population health.

(Comment 122) As FDA noted in the NPRM, one study detected diethylene glycol in one e-cigarette cartridge (79 FR 23142 at 23157). A few comments took issue with FDA's reliance on the study, because the amount of diethylene glycol reported was so low that it was unlikely to cause harm to consumers and had not been replicated in other scientific studies to date.

(Response) FDA appropriately characterized this study in the NPRM, stating that diethylene glycol "was found in only 1 of 18 cartridges studied and it was not found at all in another 16 studies" (79 FR 23142 at 23157). FDA agrees that the amount found was low, but reiterates that diethylene glycol is a toxicant and, therefore, is a cause for concern.

(Comment 123) We received many comments regarding the safety of the aerosol that is emitted from e-cigarettes. These comments expressed concern that individuals incorrectly believe that the aerosol emitted from e-cigarettes is harmless and stated that e-cigarette aerosol is not simply water "vapor," as is sometimes advertised (Ref. 151). They provided studies indicating that the primary or mainstream and exhaled or secondhand e-cigarette aerosols have been found to contain at least 10 chemicals known to cause cancer, birth defects, or other reproductive harm (Ref. 65). They also noted that potentially harmful constituents have been identified in some e-liquids and their aerosol, including tobacco-specific nitrosamines, heavy metals, and carbonyls, albeit at significantly lower levels than in cigarette smoke (Refs. 65, 118, 152, 153, 154, 155, 156). Studies have shown that the primary aerosol contains measurable amounts of nicotine, which can have an impact on both users and nonusers (Ref. 144, 147).

We also received comments stating that the aerosol is completely harmless or significantly less harmful than tobacco smoke from combusted tobacco products; the comments included data from peer-reviewed publications (Refs. 144, 156, 157, 158), a presentation at a professional conference (Ref. 159), and individual company testing. These comments also submitted research that was not peer-reviewed, which stated that there were no key tobacco smoke toxicants in e-cigarettes (Ref. 160).

(Response) FDA recognizes that the aerosol that is exhaled by users of some e-cigarettes and similar electronic apparatus may not pose as much harm as smoke emitted from combusted tobacco products. However, given that studies do indicate that both nicotine and other toxicants are found in the exhaled aerosol, limiting exposures must be considered. (See section XII regarding the potential for product standards and tobacco product manufacturing practices on manufacturers of newly deemed products.) In the absence of short- and long-term studies on the potential impact of secondary exposure to aerosol, FDA cannot conclude that the aerosol is harmless. Moreover, as stated throughout this document, the Tobacco Control Act does not require that FDA make a finding that a product is harmful in order to deem it to be subject to chapter IX of the FD&C Act; FDA is authorized to deem any product that meets the definition of a "tobacco product" pursuant to section 901 of the FD&C Act.

(Comment 124) A few comments stated that the aerosol must be safe because the primary constituents of the liquid that generate the e-cigarette aerosol are propylene glycol and glycerin. They stated that inhalation of such constituents is harmless because they are designated as "generally recognized as safe" (GRAS) by FDA. They cited animal inhalation studies showing limited toxicological effects from either propylene glycol or glycerin (*e.g.*, Ref. 161).

(Response) FDA disagrees with comments claiming that the aerosol is safe due to certain components being recognized as GRAS. It is important to note that the definition of food additive in section 201(s), and its exclusion of GRAS substances, relates to intended uses that may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (section 201(s) of the FD&C Act). E-liquid is not food or intended for ingestion; therefore, the fact that propylene glycol and glycerin have been designated GRAS for food does not necessarily mean that these components are safe for inhalation. (See additional responses in this section of the document regarding FDA's concerns with ENDS aerosol.)

(Comment 125) Several comments that stated that e-cigarettes are harmless cited one study in which the author concluded that there "is no serious concern about the contaminants such as volatile organic compounds" in the e-cigarette "vapor" and that tobacco-specific nitrosamine (TSNA) levels in the "vapor" are just as hazardous as those TSNAs in NRT products (Ref. 162). Some of these comments specifically asked why FDA did not include this study in the proposed deeming rule.

(Response) FDA has considered these findings and agrees that the exhaled aerosol from ENDS users is potentially less hazardous than secondhand smoke from combusted cigarettes. However, FDA disagrees with the author's conclusion that exposure to aerosol ("vapor") "pose[s] no apparent concern" (Ref. 162). FDA recognizes that the aerosol that is exhaled by users of some e-cigarettes and similar electronic apparatus may not pose as much harm as smoke emitted from combusted tobacco products. However, given that studies do indicate that both nicotine and other toxicants are found in the exhaled aerosol, limiting exposures must be considered. FDA has repeatedly noted the potential benefits and need for additional information regarding ENDS and, therefore, the research included in the NPRM accurately summarized the state of the research on e-cigarettes (and the other newly deemed products) at the time it was drafted.

(Comment 126) A few comments claimed that there are many e-liquids on the market that do not contain nicotine and, therefore, e-liquids should not be regulated. Other comments provided studies that showed that e-cigarettes deliver nicotine but noted that delivery is dependent on the e-cigarette apparatus and liquid type, the rate at which the nicotine is delivered, and the user's experience with e-cigarette use (Ref. 130).

(Response) FDA is aware that, although some ENDS and e-liquids are *marketed* as nicotine free, as stated in section VIII.D, studies have found that certain types of ENDS do not have consistent quality and the labels may not accurately reflect the amount of nicotine in the e-liquid. The World Health Organization (WHO) also has noted that the level of nicotine delivered in currently marketed ENDS varies widely depending on product characteristics, user puffing behavior and nicotine solution concentration, leaving smokers unaware of the nicotine levels they are receiving (Ref. 163). In addition, FDA agrees that many factors influence the delivery of nicotine. For example, an experienced ENDS user may be exposed to amounts of nicotine similar to those delivered by cigarette smoking (Ref. 114). Also, as stated earlier, nicotine-free e-liquid that is intended or reasonably expected to be used with or for the human consumption of tobacco products in most cases would be a component or part of a tobacco product and, therefore, within the scope of this rule. These products will be evaluated on a case-by-case basis.

(Comment 127) Many comments discussed the possibility of nicotine poisoning due to improper access to, or use of, e-liquids. Most of these comments expressed concerns about the growing number of calls to poison control centers due to accidental nicotine poisoning. Others believed this concern was overstated and noted that many drugs can cause poisoning if stored improperly. They stated that the addition of child-resistant containers would alleviate this concern. Some also noted that e-cigarette users self-titrate the nicotine dosage, so concerns about overdosing should be minimal (Ref. 84).

(Response) FDA is concerned about the risk of nicotine poisoning in both users and nonusers. The CDC has reported more than 2,400 calls to U.S. poison control centers for e-liquid exposure between September 2010 and February 2014 (Ref. 164). In another study of 1,700 e-liquid exposures reported to U.S. poison control centers from June 2010 through September 2013, children 5 years of age or younger represented the largest proportion of e-liquid exposures and the group with the greatest increase in exposures per month in the first three quarters of 2013 (Ref. 165). Studies show that nicotine in sufficient concentrations, either when ingested or in contact with the skin, can result in serious or fatal poisoning and is concerning (Refs. 166, 167). Symptoms of toxicity include nausea, vomiting, seizures, coma, cardiovascular instability, respiratory arrest, and sometimes death. Although there was disagreement among the comments as to the level of nicotine that causes poisoning, the nicotine content of many refillable vials could be toxic to adults and children regardless of the measurement used. Accordingly, elsewhere in this issue of the **Federal Register**, FDA has made available draft guidance, which when final will describe FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products, including recommendations for exposure warnings and child-resistant packaging that would help support a showing that the marketing of a product is appropriate for the protection of the public health. In addition, FDA issued an ANPRM prior to this deeming rule, seeking comments, data, research, or other information that may inform regulatory actions FDA might take with respect to nicotine exposure warnings and child-resistant packaging.

(Comment 128) Some comments compared the poison risks of nicotine against other household products, noting that the incidence of nicotine poisoning is significantly lower than for other household products (Ref. 168).

(Response) Regardless of the incidence of nicotine poisoning in comparison to poisonings attributed to other household products, the dramatic rise in nicotine poisoning from e-liquid exposures is very concerning. FDA is taking under advisement the submitted data regarding nicotine poisoning and suggestions for measures that FDA can take in a separate rulemaking to address the issue, including establishment of tobacco product manufacturing practice regulations under section 906(e) and tobacco product standards under section 907 of the FD&C Act. In addition, as stated previously, FDA issued an ANPRM prior to this deeming rule seeking comments, data, research, or other information that may inform regulatory actions FDA might take with respect to nicotine exposure warnings and child-resistant packaging. Moreover, elsewhere in this issue of the **Federal Register**, FDA has made available draft guidance, which when final will describe FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products, including recommendations for exposure warnings and child-resistant packaging that would help support a showing that the marketing of a product is appropriate for the protection of public health.

(Comment 129) Comments were divided as to whether nicotine is dangerous to humans. Some comments stated that liquid nicotine is completely benign (and that FDA should not regulate e-cigarettes given the lack of harms). They claimed that FDA's findings regarding NRTs illustrate that nicotine is not carcinogenic to humans. (See "Modifications To Labeling of Nicotine Replacement Therapy Products for Over-the-Counter Human Use," 78 FR 19718, April 2, 2013.) Other comments stated that although nicotine has some side effects, it is significantly less hazardous than the toxicants ingested with combusted products. Still others claimed that nicotine is very dangerous.

Comments that claimed that nicotine is dangerous cited studies showing that although nicotine may not be a primary carcinogen, it likely promotes cancers established through angiogenic (promoting of blood vessels in tumors) effects (*e.g.*, Ref. 169). The comments also noted that the 2014 Surgeon General's Report stated that the health risks of nicotine are more serious than previously thought and that FDA should consider this when evaluating the impacts of the newly deemed products on vulnerable populations. Others believed that nicotine is so dangerous that individuals should be required to obtain a certification before being permitted to acquire and handle it.

(Response) In the proposed deeming rule, FDA recognized the impact of nicotine on a youth's brain (see 79 FR 23142 at 23153 and 23154) and also noted poisoning concerns. The inhalation of nicotine (*i.e.*, nicotine without the production of combustion) is of less risk to a user than the inhalation of nicotine delivered by smoke from combusted tobacco products. However, limited data suggests that the pharmacokinetic properties of inhaled nicotine can be similar to nicotine delivered by combusted tobacco products. Thus, inhaled nicotine from a non-combustible product may be as addictive as inhaled nicotine delivered by combusted tobacco products. Researchers recognize that the effects from nicotine exposure by inhalation are likely not responsible for the high prevalence of tobacco-related death and disease in this country (Refs. 10, 11). Although nicotine has not been shown to cause the chronic disease associated with tobacco use, the 2014 Surgeon General's Report noted that there are risks associated with nicotine (Ref. 9 at 111). For example, nicotine at high enough doses has acute toxicity (id.). Nicotine exposure during fetal development has lasting adverse consequences for brain development (id.). Nicotine also adversely affects maternal and fetal health during pregnancy, contributing to multiple adverse outcomes such as preterm delivery and stillbirth (id.). Further, data suggest that nicotine exposure during adolescence may have lasting adverse consequences for brain development (id.). Some studies also have found that nicotine can have detrimental effects on the cardiovascular system and potentially disrupt the central nervous system (Refs. 14, 15). See also section VIII.C discussing the increase in poisoning due to accidental nicotine ingestion.

FDA is not stating that nicotine is harmless. Unlike ENDS, which have not been reviewed by FDA, the NRT products mentioned in the comments are regulated and have undergone premarket review by FDA's Center for Drug Evaluation and Research (CDER) and been found to be safe and effective before obtaining authorization to enter the market (sections 505 and 506 of the FD&C Act). The Agency does not have sufficient data to be able to conclude that consumers are inhaling only nicotine, and no other chemicals or toxicants, when using ENDS. Although ENDS likely do not deliver the same level of toxicants as cigarettes, studies show that there are dangers associated with ENDS use and that exhaled aerosol is not simply "water vapor," as some believe. (See section VIII.C for additional discussion about the toxicants in ENDS vapor.)

(Comment 130) At least one comment suggested that to help address the dangers of nicotine and its use in future tobacco products, manufacturers registering future products with FDA should provide documents demonstrating the accuracy of stated nicotine levels and that the products are diacetyl and acetyl propionyl free.

(Response) FDA agrees with the need to carefully monitor future tobacco products and to evaluate the toxicological concern of chemical ingredients, such as diacetyl and acetyl propionyl, in e-liquids and that statements about the nicotine concentration in the e-liquid as well as the amount of nicotine that will be delivered to the user are accurate. FDA's review of SE reports and PMTAs under sections 905 and 910 of the FD&C Act will often include analysis of the chemicals included in the products. In addition, the requirements to submit ingredient listings under section 904 and HPHC testing data under sections 904 and 915 are expected to alert FDA to the existence of these HPHCs in e-liquids.

(Comment 131) Many comments expressed concerns regarding the high cost associated with testing for HPHCs in each individual e-liquid and e-cigarette product. They suggested that FDA use enforcement discretion, as the Agency has done previously, to reduce the regulatory burden for e-cigarette manufacturers. For example, they noted that FDA has compliance policies for the submission of SE reports for certain product modifications and HPHC reporting. To reduce the regulatory burden, they suggested that FDA not require ingredient disclosure of all unique e-liquid products under section 904(a)(1) of the FD&C Act because such a requirement is unreasonable given the many different e-liquid formulations in these retail establishments. They stated that in lieu of ingredient listings, FDA should accept a table of all ingredients used in e-liquids along with use-level (concentration) ranges (*i.e.*, minimum and maximum percentages) of those ingredients in their products. These comments further suggested that FDA allow companies to simply amend their ingredients lists when altering products rather than requiring them to submit PMTAs.

(Response) Once this rule becomes effective, newly deemed products automatically become subject to chapter IX and all of its provisions applicable to tobacco products, without exception. Therefore, all manufacturers and importers of the newly deemed products will be subject to the requirements under sections 910, 905, and 904 of the FD&C Act upon the effective date of this final rule.

However, FDA has established a compliance policy for certain circumstances. See section IV.D describing the compliance policy regarding certain provisions and small-scale tobacco product manufacturers.

D. Quality Control

In the NPRM, FDA recognized previous instances of lack of quality control for certain e-cigarette products (79 FR 23142 at 23149). FDA indicated that the premarket review requirements that will automatically apply to the newly deemed products can help to address quality control concerns.

(Comment 132) Many comments expressed concern regarding the lack of controls in place for the mixing of e-liquids. They stated that these liquids are often mixed by individual consumers or employees of e-cigarette retail establishments who may lack training or knowledge of guidelines for handling such products. Several retailers of e-liquids submitted comments stating that they have controls in place to ensure the safety of their e-liquids.

(Response) FDA understands the comments' concerns about the safety of e-liquids. As stated previously, FDA issued an ANPRM prior to this deeming rule seeking comments, data, research, or other information that may inform regulatory actions FDA might take with respect to nicotine exposure warnings and child-resistant packaging. Also, elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a draft guidance, which when finalized will provide FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products, including recommendations for exposure warnings and child-resistant packaging that would help support a showing that the marketing of a product is appropriate for the protection of public health. FDA also intends to consider these and other issues during its premarket review of these products. Further, after the effective date of this rule, FDA can exercise its authorities under the Tobacco Control Act to take additional steps to address the safety of e-liquids.

(Comment 133) Some comments included data regarding the variations among the nicotine levels in e-liquids, including data showing that the nicotine levels of the products are not accurately reflected in the nicotine concentration stated on the labels. For example, one study found nicotine content labels to be highly inaccurate and determined that products claiming to be nicotine-free actually contained high levels of nicotine (Ref. 170). Other comments stated that the variations are no longer as significant among the newer e-cigarette products, and that newer studies reported more consistent nicotine levels (Ref. 171).

Many comments cited several studies of newer e-cigarettes which continued to find wide variability in e-cigarette engineering, including nicotine concentrations in e-liquid, that were inconsistent with the information contained on the product label (Ref. 16). For example, one 2014 study of e-liquid refills found that the actual nicotine level of 65 percent of the e-liquids deviated by more than 10 percent from the nicotine concentrations printed on the labels (Ref. 17). Other studies found variability among nicotine concentrations, but the nicotine levels were equivalent to or lower than advertised (Refs. 18, 19). In one study, researchers stated that the total amount of nicotine in the e-liquid studied was potentially lethal if an individual were to drink it or absorb it through the skin (Ref. 18). They based this finding on the lethal level of nicotine being in the 10 to 60 milligram (mg) range; however, other comments claimed the lethal dose of nicotine is actually much greater (Ref. 172).

Some comments expressed concern that this rule does not address the possibility of a dangerous contamination of a batch of e-liquid because it does not include quality control measures or product standards that could prevent such contamination. They believed that FDA's authority to establish tobacco product manufacturing requirements or product standards in the future was insufficient to address this concern.

(Response) FDA is aware of the variability of nicotine among certain ENDS and that the labeling may not accurately reflect the nicotine levels. After this rule becomes effective, FDA has the authority to issue tobacco product manufacturing practice regulations under section 906(e) of the FD&C Act to address this issue. The PMTA process (particularly, the requirement to submit information on manufacturing methods) also provides a mechanism through which products that are more harmful or addictive than products on the market at the time of submission would be denied entrance to the market. Moreover, immediately upon the effective date of this rule, if FDA determines that an e-liquid has been contaminated and is therefore adulterated under section 902 or that it is misbranded under section 903 of the FD&C Act because its labeling is false or misleading, it can initiate enforcement action such as a seizure, injunction, or criminal prosecution.

(Comment 134) A few comments expressed concern that FDA may limit the availability of e-liquids to established manufacturers only and prohibit individuals from mixing their own e-liquids. These comments stated that they need access to products of reasonable potency, high purity, and high quality.

(Response) This final deeming rule places some restrictions on the sale and distribution of tobacco products, such as minimum age restrictions, but it does not bar sales to individuals generally.

(Comment 135) At least one comment noted that, although there have been fires due to mishandling of e-cigarette batteries, cases of accidental poisoning, and concerns about functionality, the "de facto regulations" that are in place, "namely brand equity, potential civil liability, and word-of-mouth" have been effective in helping the market evolve and controlling behavior.

(Response) FDA disagrees. FDA's adverse event reporting system has inherent limitations as a measure of the impact of e-cigarettes since ENDS are a newly deemed product and reporting adverse events associated with tobacco products (including e-cigarettes and other ENDS) is voluntary. FDA remains concerned about adverse events associated with ENDS use, including overheating and exploding batteries as reported in the news, and the vast evidence that accidental nicotine poisoning is increasing in the wake of growing e-cigarette use. Toward that end, elsewhere in this issue of the **Federal Register**, FDA has made available draft guidance, which when final will describe FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products, including compliance with existing voluntary standards for ENDS batteries. In addition, concerns remain regarding quality control, which could impact the functionality of these products. FDA believes that the automatic statutory provisions that will apply to these products as a result of this deeming rule, in conjunction with additional authorities under the law that FDA can exercise after the effective date, will help address these concerns.

(Comment 136) At least one comment sought clarification as to why FDA expressed concern about quality control issues for e-cigarette products but not for combusted products that contain thousands of toxic constituents.

(Response) FDA is concerned about quality control for all tobacco products and will continue to monitor these products to determine if there are quality control issues. FDA's premarket review of the newly deemed products will increase product consistency. For example, FDA's oversight of the constituents of e-cigarette cartridges would help to ensure quality control related to the chemicals and their quantities being aerosolized and inhaled. Quality control issues will also be addressed in a tobacco product manufacturing practices regulation that FDA intends to issue at a later date. Also, FDA may take enforcement action if an ENDS or any other tobacco product is adulterated or misbranded within the meaning of the FD&C Act.

(Comment 137) A few comments expressed concerns regarding the quality of e-cigarettes manufactured overseas. They stressed the importance of issuing regulations to require the registration of foreign establishments so that FDA knows the identity of foreign manufacturers and the products they import into the United States.

(Response) FDA agrees with comments' concerns regarding quality control and the safety of ENDS manufactured both domestically and in other countries. One of the immediate benefits of deeming ENDS is that all newly deemed products, including ENDS, that meet the definition of "new tobacco product" will be subject to the premarket authorization requirements in sections 905 and 910 of the FD&C Act. In addition, FDA has announced its intention in the Unified Agenda to issue a NPRM that would apply the registration and listing requirements of section 905 to foreign establishments.

(Comment 138) Some comments suggested that to properly regulate e-cigarettes, given their position on the continuum of nicotine-delivering products, FDA should regulate these products based on the size of the manufacturer—which is generally smaller than the size of companies that manufacture cigarettes and smokeless tobacco products. They also suggested that FDA stagger the compliance periods for submission of PMTAs so that smaller companies have additional time to prepare their submissions.

(Response) Section IV.D has additional information about compliance periods for small-scale tobacco product manufacturers. FDA's compliance policy for the submission of SE reports, SE exemption requests, and PMTAs for all manufacturers of deemed products is included in section IV.C.

(Comment 139) One comment recommended that FDA collaborate with other Federal Agencies, including the National Institutes of Health (NIH), CDC, and the Substance Abuse and Mental Health Services Administration (SAMHSA), as well as international agencies including the EU, to continue research on tobacco products and increase surveillance and other enforcement of quality control and other issues.

(Response) FDA agrees. FDA intends to continue to review available studies and fund studies on tobacco products, including studies on ENDS initiation, use (including transitions to other tobacco products and multiple use), perceptions, dependence, and toxicity (Ref. 173). FDA also has been conducting a series of public workshops to obtain additional information on e-cigarettes and their impact on public health (79 FR 55815). These workshops will help to inform FDA's development of future rules and policies that have an impact on ENDS. Additional regulations regarding ENDS will be subject to the requirements of the APA.

(Comment 140) Some comments stated that FDA should regulate materials used in the manufacture of e-cigarette components and packaging that come into direct contact with e-liquids. They noted that improper e-cigarette construction and e-liquid packaging materials could also result in hazardous leachates or degradation of products in the e-liquid that may become aerosolized and inhaled upon use.

(Response) With this final rule, FDA is deeming all products, except for accessories of newly deemed products, that meet the definition of "tobacco products" under section 201(rr) of the FD&C Act, which includes the components and parts (including packaging of such products). FDA will consider the issues raised by the comments when it develops a NPRM on tobacco product manufacturing practices.

E. Misperceptions

In the NPRM, FDA noted its concerns regarding consumer misperceptions of currently unregulated products, particularly e-cigarettes. Many comments provided data to substantiate those concerns and others provided data and personal stories regarding the potential benefits of e-cigarettes. Other comments indicated that, based on these potential benefits, they believed e-cigarettes to be safe tobacco products.

(Comment 141) Many comments stated, but did not provide supporting data, that e-cigarettes: (1) Are approximately 99 percent less hazardous than cigarettes; (2) are only consumed by smokers and former smokers who quit by switching to e-cigarettes; and (3) have not been found to create nicotine dependence in any nonsmoker. They also stated that there is no evidence that ingesting e-liquid leads to fatalities.

(Response) As discussed throughout this document, FDA agrees that use of ENDS is likely less hazardous for an individual user than continued smoking of traditional cigarettes. One self-selected comparison reported that across several Japanese brands, under some use conditions, ENDS released 1/50th of the level of formaldehyde released by cigarettes (Ref. 135). The highest level detected was six times lower than the level in cigarette smoke (id.). But other research, published as a letter to the editor of the *New England Journal of Medicine*, reported that ENDS operated at 5 volts delivered a mean of 390+/−90 μg per 10 puff sample which is greater than 150 μg, the estimated average delivery of formaldehyde than conventional cigarettes (Ref. 128). No formaldehyde-releasing agents were detected when ENDS were operated at

3.3 volts (Ref. 128). A subsequent peer-reviewed article on 5 variable-power ENDS devices found large variations in formaldehyde delivery across devices (Ref. 129). The first device yielded more formaldehyde than combustible cigarettes at every power level tested, and the second device delivered more formaldehyde at the highest power level tested; the remaining three devices delivered less formaldehyde than combustible cigarettes at all power levels tested (*id.*) The same research found that aldehyde delivery varied by 750-fold from one ENDS device to another (*id.*). The article referenced in one comment (Ref. 67) reported that increasing the voltage from 3.2 to 4.8 volts increased formaldehyde, acetaldehyde, and acetone levels from 4 to over 200-fold.

Nevertheless, as discussed in section VIII.F, evidence shows that while most ENDS are consumed by smokers and former smokers (*e.g.,* Refs. 109, 110), some consumers (including youth and young adults) are initiating tobacco use with ENDS. Several studies have found that ENDS users, particularly experienced ENDS users, are able to achieve nicotine exposures similar to cigarette smokers (Refs. 114, 148, 149, 150). Although no studies have been done to-date assessing the development of dependence among non-smokers, several studies have found that ENDS users, particularly experienced ENDS users, are able to achieve nicotine exposures similar to cigarette smokers and that nicotine is a known addictive substance. Fourth, as discussed in section VIII.D, the incidence of nicotine poisoning has been on the rise and has resulted in severe poisonings and hospitalization (Ref. 174). In December 2014, after the close of the comment period for the NPRM, media reported the first death of a toddler from accidental poisoning from e-liquid (Ref. 175). Regulation of ENDS will help to alleviate consumer misperceptions such as those expressed in the comments.

(Comment 142) Many comments stated that e-cigarettes should be regulated given their appeal to youth and young adults and the belief that e-cigarettes are less harmful than conventional cigarettes. They agreed with FDA's concern that a failure to regulate the newly deemed products could reinforce consumers' existing confusion and misinformation about these products. However, other comments stated that FDA's concerns about youth's misperception of the safety of e-cigarettes should not be a factor in FDA's decision to regulate them. They stated that regulation cannot remedy the fact that many youth affirmatively disregard available safety information.

(Response) As FDA stated in its proposal, many people may believe that certain tobacco products covered by this rule present fewer health risks when compared to that of cigarettes (79 FR 23142 at 23158 and 23159), which is supported by some of the emerging scientific literature demonstrating that some ENDS products, operated at some power levels, may have lower delivery of harmful constituents and toxicants than that of combusted cigarettes (see discussion on the health harms of ENDS in response to Comment 117). In fact, a recent telephone survey of 1,014 adults indicates that a majority of American adults surveyed (nearly two-thirds, 65 percent) believe e-cigarettes are harmful to the health of the people who use them and 23 percent believe that they are not harmful (Ref. 176). In addition, 44 percent believe that electronic cigarettes are less harmful than combusted cigarettes while 32 percent thought they were equally harmful (id.). Of particular note, the survey found that "[t]hose who have ever used e-cigarettes are significantly less likely than never-users to believe that e-cigarettes and marijuana are harmful to the health of people who use them, and more likely to believe in the benefits of e-cigarettes when it comes to smoking cessation" (id.).

Although FDA expects that youth understanding and appreciation of the health effects and risks of certain newly deemed tobacco products will be improved if they are also FDA-regulated, that is only one of the many public health benefits that will accrue from deeming them subject to the FD&C Act, as discussed in the NPRM (79 FR 23142 at 23148 and 23149).

(Comment 143) Some comments expressed concern that the increase in e-cigarette use in places where cigarette smoking is not currently allowed creates confusion, particularly among children, who often cannot tell the difference between smoking and e-cigarette use. They referred to unpublished research and anecdotal evidence indicating that when children see pictures of people using e-cigarettes they report that someone is smoking.

Other comments disagreed, stating that e-cigarette use will more likely lead to normalization of e-cigarettes rather than cigarettes (Ref. 110). They stated that one study found that daily smokers (aged 18 to 35 years) who observed individuals using e-cigarettes only increased the smoker's desire for an e-cigarette, and not for a conventional cigarette (Ref. 177).

(Response) FDA is concerned that the growth in ENDS use, particularly among youth and young adults, could lead to the re-normalization of cigarette smoking. The Surgeon General recognized that adolescents are particularly vulnerable to visual cues to smoke and to social norms, making this an even greater concern (Ref. 49). FDA believes that subjecting ENDS to its tobacco control authorities, and requiring compliance with the various statutory and regulatory requirements (*e.g.,* ingredient listing and others), will help to address the common misunderstanding that these products are safe to use.

F. Use as a Cessation Product

In the preamble to the NPRM, FDA recognized that some consumers may use ENDS in tobacco cessation attempts. We note that if an ENDS product seeks to be marketed as a cessation product, the manufacturer must file an application with FDA's Center for Drug Evaluation and Research (CDER) and no ENDS have been approved by FDA as effective cessation aids.

Recently published population-wide data from the CDC's NCHS, which provides the first estimates of e-cigarette use among U.S. adults from a nationally representative household interview study, indicates that current cigarette smokers and recent former smokers (*i.e.,* those individuals who quit smoking within the past year) were more likely to use e-cigarettes than long-term former smokers (*i.e.,* those individuals who quit smoking more than one year ago) and adults who had never smoked (Ref. 24). Among current cigarette smokers who had tried to quit smoking in the past year, more than one-half had ever tried an e-cigarette and 20.3 percent were current e-cigarette users (id.).

(Comment 144) Comments were divided regarding the viability of e-cigarettes as a smoking cessation product. Some comments contended that the actual patterns of e-cigarette use, citing a meta-analysis showing the rapid penetration of the youth market and high levels of dual use among both adults and adolescents, will lead to a lower probability that smokers using e-cigarettes will quit smoking cigarettes (Ref. 16). They also cited another study in which, although 85 percent of e-cigarette users reported that they were using e-cigarettes to quit smoking, they were no more likely to have quit smoking than nonusers of e-cigarette (Ref. 178).

However, consumers and manufacturers of e-cigarettes provided information showing positive impacts of e-cigarettes on cessation, including personal anecdotes from former smokers (Ref. 132). For example, they cited a 1-year multinational study where researchers found that among smokers who were using e-cigarettes at the baseline, 22 percent had quit smoking after 1 month and 46 percent had quit smoking after 1 year (Ref. 179). In a survey of adults in the United Kingdom who tried to quit smoking at least once in the past year, respondents who used e-cigarettes had a higher quit rate (20 percent) than those who used NRTs like patches or gum (10 percent) or those that did not use a cessation aid (15 percent) (Ref. 180). These comments also asserted evidence that e-cigarette use, at a minimum, leads to decreased cigarette use (*e.g.,* Refs. 107, 181). One comment also noted that tribes use e-cigarettes as an alternative to smoking and to promote cessation.

(Response) As we have stated throughout this document, we recognize that there is emerging data that some individual smokers may potentially use ENDS to transition away from combustible tobacco products. For instance, prospective studies of varying duration examining the efficacy of e-cigarettes as cessation devices suggest their potential to decrease combustible cigarette use as well as promote abstinence from combustible cigarettes (Refs. 107, 149, 182, 183, 184). Three randomized controlled clinical trials (Ref. 107, 149, 184) report that e-cigarettes may help some smokers to stop smoking. The trial that compared e-cigarettes to nicotine replacement therapy found verified abstinence in all experimental groups, but no significant difference among e-cigarettes, placebo e-cigarettes (*i.e.,* e-cigarettes with no nicotine), and nicotine patches in six-month abstinence rates (Ref. 184). Achievement of abstinence was substantially lower than the optimistic estimates on which the power calculation and study sample size were based, and thus, the researchers could conclude no more than that "among smokers wanting to quit, nicotine e-cigarettes might be as effective as patches for achieving cessation at 6 months" (id.). It is possible that longer term prospective studies may—or may not—demonstrate statistically significant cessation outcomes for e-cigarettes in relation to conventional nicotine replacement therapies (id). It is noteworthy that a third of the participants allocated to the e-cigarettes groups in this study reported continued product use at 6 months, suggesting that they might have become long-term e-cigarette users (id.). However, some systematic reviews of available evidence indicate that there is currently insufficient data to draw a conclusion about the efficacy of e-cigarettes as a cessation device (Refs. 185, 186). The Cochrane Collaboration's systematic review and meta-analysis assessed approximately 600 scientific records to include two randomized controlled trials and 11 cohort studies on e-cigarettes and smoking cessation in their review (Ref. 186). As the Cochrane review judged RCTs to be at low risk of bias, the investigators combined results from two randomized controlled trials, totaling over 600 people, and conducted a quantitative meta-analysis. Results indicated that using e-cigarettes with nicotine was associated with increased smoking cessation as compared with e-cigarettes without nicotine. Investigators also found evidence that using e-cigarettes with nicotine also helped more smokers reduce the amount they smoked by at least half compared to e-cigarettes without nicotine. However, the authors cautioned that "the small number of trials, low event rates and wide confidence intervals around the estimates mean that our confidence in the result is rated 'low'." (Ref. 186) In addition, the authors observed that "the overall quality of the evidence for our outcomes was rated 'low' or 'very low' because of imprecision due to the small number of trials" (id.). Another meta-analysis of the same two trials of e-cigarettes with and without nicotine found comparable results (Ref. 187). The authors also reported a pooled estimate of cessation among nicotine e-cigarette users, but the lack of non-e-cigarette control groups in the studies prevented them from comparing the efficacy of e-cigarettes against no e-cigarette use and against standard interventions for cessation, such as nicotine patches (id.).

An alternate systematic review and meta-analysis of approximately 600 scientific records to include 15 cohort studies, 3 cross-sectional studies, and two clinical trials (one RCT, one non-RCT) examined the association between e-cigarette use and cessation in observational epidemiological studies and clinical trials; all 20 studies compared smoking cessation rates for e-cigarette users against control groups of smokers who did not use e-cigarettes (Ref. 112). This meta-analysis found overall that odds of quitting cigarettes were on average 28 percent lower for smokers who used e-cigarettes than those who did not (odds ratio = 0.72, with 95 percent confidence interval 0.57 to 0.91) (Ref. 112). Of note, this meta-analysis included chiefly observational studies whose control groups were not randomized, and included a wide range of designs as well as variable exposures and outcome definitions (id.). While some potential confounders were controlled for in most of the studies, the investigators acknowledged that there may be other unidentified confounders that could be a source of bias. This potential bias as well as other limitations described may impact interpretability of the overall findings (id.).

We also note that ENDS have not been approved as effective cessation aids. FDA remains committed to supporting long-term population-level research that will help fill in current data gaps.

(Comment 145) At least one comment suggested that FDA provide physicians with guidelines about e-cigarette use, including its health impact and efficacy as a cessation tool.

(Response) To the extent the comment is about ENDS products that are drugs because they are marketed for cessation, an ENDS product marketed for therapeutic purposes is a drug or device subject to FDA's regulations and laws for those products.

(Comment 146) A few comments expressed concern that FDA misrepresented certain studies in the NPRM and would not consider research released since the issuance of the NPRM, particularly regarding the effectiveness of e-cigarettes as a cessation tool.

(Response) FDA has considered the preliminary evidence regarding the effectiveness of ENDS to help smokers quit or to reduce their consumption of combusted tobacco products. There is some indication that such products may have the potential to help some individual users to quit using combusted tobacco products or to reduce their use of such products, as reported by scientific literature describing a small number of randomized controlled trials evaluating the impact of ENDS use on smoking outcomes (Refs. 137, 148, 184) and pilot studies evaluating ENDS use on smoking reduction and cessation (Refs. 182, 183). But other evidence is to the contrary. Beyond the meta-analysis discussed in section V(B)(3), a year-long study of over 5,000 20-year-old Swiss men found that, even after adjusting for nicotine dependence, individuals who were smokers at the start of the study and who reported e-cigarette use at the end of the study were more likely to still be smoking and more likely to have made one or more unsuccessful quit attempts at the end of the year than individuals who were smokers at the start and who reported no e-cigarette use (Ref. 188). The most important consideration is that ENDS are not an

FDA-approved cessation product. If an ENDS manufacturer wishes to make a cessation claim or otherwise market its product for therapeutic purposes, the company must submit an application for their ENDS to be marketed as a medical product.

(Comment 147) Some comments expressed concern that e-cigarette users are developing an addiction to nicotine while seeking to overcome their smoking addiction and that the lack of regulation makes it difficult for users to know the nicotine level that they need in their e-cigarettes to overcome their addiction. They stated that for cigarette smokers who are trying to replace their cigarette-derived nicotine with e-cigarettes, ingredient listing and other requirements are vital to ensure that users know how much nicotine they are ingesting.

(Response) By deeming ENDS, FDA has ensured that these products are now subject to requirements related to ingredient and HPHC reporting, among other requirements. In addition, the registration and listing requirements and premarket applications will provide FDA with vital information as to the extent of ENDS use and how many ENDS products consumers are using on a daily basis.

(Comment 148) Some comments perceived the newer generation of e-cigarettes to be less addictive than combusted cigarettes and closer in profile (including risk profile) to NRTs (Ref. 76). They noted the limited number of significant adverse events resulting from e-cigarette use and claimed that such adverse events are not distinguishable from NRTs (Ref. 184). Some comments also believed that FDA should consider the advantages that e-cigarettes have (as compared to NRTs) when establishing the regulatory approach for these products, including the fact that they offer appealing visual, tactile, and gestural similarities to cigarettes, and that e-cigarettes provide quicker nicotine delivery than NRTs (Ref. 189).

(Response) As we have stated throughout this document, we recognize that individual smokers may report cessation benefits from ENDS and that preliminary research outcomes from randomized controlled trials indicate that ENDS may decrease some individuals' cigarette consumption and promote cessation. However, the risk profile is likely to be different as compared to NRTs, and the long-term risks associated with chronic use of ENDS are unknown. Finally, contrary to ENDS, the nicotine patch and other NRTs were found to be safe and effective by FDA's CDER after reviewing premarket applications containing data and information establishing safety and effectiveness. No ENDS has yet been approved by CDER.

(Comment 149) Comments in support of limited or no regulation of e-cigarettes stated that these products have a positive impact on the public health at the population level. They cited online surveys and convenience store data showing that most e-cigarette users do not use additional tobacco products (see section VIII.H) and claimed that FDA cherry-picked the evidence regarding dual use in the NPRM. They also claimed FDA did not adequately assess the reduction in smoking that would result from increased e-cigarette use and, as a result, the Agency underestimated the potential positive impacts of e-cigarettes on the public health at the population level.

(Response) Many provisions of the FD&C Act call for a population-level public health analysis that takes into account the population as a whole, including users and nonusers of tobacco products (*e.g.,* section 906(d) of the FD&C Act). Even products that are less toxic than combusted tobacco products on an individual user basis may increase public health harms if, for example, they encourage nonusers to start using tobacco products that can lead to lifelong nicotine addiction.

As we have stated throughout the document, FDA has examined data regarding health harms generally associated with all of the categories of tobacco products regulated under this rule (including ENDS, which FDA recognizes may potentially provide cessation benefits to some individual smokers). FDA is regulating these products in accordance with this knowledge and will continue to regulate as we learn more about the potential for product-specific health harms. FDA recognizes that some ENDS users report that the products have the potential to help individual users to quit smoking. However, FDA's responsibility is to assess the population health impact of ENDS, including increasing youth use, as well as the frequency of dual use of ENDS and combusted tobacco products. FDA believes that data from long-term population level studies, such as the PATH Study, will help to provide information about the overall population health impacts of ENDS.

(Comment 150) Many comments provided personal stories and peer-reviewed studies to illustrate the benefits of e-cigarettes as a cessation product and to request that FDA treat this product category differently based on where the product falls within the continuum of nicotine delivering products. For example, they suggested that FDA differentiate between substances that contain tobacco and those that are derived from tobacco and provide a separate regulatory approach for each product category.

Some comments also suggested that FDA tailor its regulatory approach based on the type of electronic apparatus—*e.g.,* advanced refillable personal vaporizers (ARPVs) or open-system vapor products versus "cigalike" products (ready for use products that look like cigarettes and are sold in convenience stores). These comments believed FDA should only deem "cigalike" products that are ready for consumption, because they are easily accessible to youth and have been associated with quality control issues (see section VIII.D). They noted that ARPVs and other open systems are significantly more expensive than "cigalike" products and are only offered in vape or specialty shops. They compared this to Option 1 (to deem all cigars) and Option 2 (to deem all cigars except premium cigars) and suggested that FDA should have provided similar options for regulating different e-cigarettes. They also expressed the need for a different regulatory approach for ARPVs because they provide users with the best opportunity to cease using combusted tobacco products (Ref. 190). However, other comments provided focus group research in which smokers rated cigalikes to be significantly more satisfying than ARPVs and asked for a minimal regulatory approach for cigalikes.

Further, some comments stated that it was not feasible to regulate ARPVs. They stated that the wide varieties of e-liquids available at e-cigarette retail establishments and the ability of users to customize their experience, including by altering the product's voltage/wattage, puff duration, coil resistance, cartridge/battery duration, and design aesthetics, make oversight, application review, and other regulation untenable.

Other comments stated that, instead of establishing a different regulatory approach, FDA should ban ARPVs because there is greater risk associated with their use and children may tamper with them. They suggested that if FDA does not ban these products, FDA should require the disclosure of all ingredients in e-liquids and other vaporized nicotine products in both their pre-use and vapor states.

(Response) To the extent that comments are asserting that FDA should not regulate ENDS or subject them to certain provisions, FDA disagrees with these comments, especially given that

ENDS use among youth and young adults is increasing. Although recent data on young adults and adults indicate that ENDS users are more likely to be former cigarette smokers and current cigarette smokers who have tried to quit (*e.g.,* Ref. 24), there is still some use among adult non-tobacco users, particularly among young adults. In addition, the rapid increase in use among adolescents is concerning. FDA also remains concerned that ARPVs present the risk of accidental nicotine poisoning. In addition, researchers recently reported that the new generation of high voltage ENDS may put users at increased risk of negative health effects (Ref. 67) and that ARPVs have the potential for increased abuse liability (*e.g.,* Refs. 109, 132, 171). FDA will continue to monitor research regarding the health effects of different types of ENDS and may tailor the regulatory requirements accordingly.

(Comment 151) Some comments requested that FDA either exempt e-cigarette products from the deeming regulation or strike the entire proposal for e-cigarettes and replace it with what they considered a more science-based approach or with rules that address good manufacturing practices and consumer safety, given their potential for use as cessation products.

(Response) FDA disagrees. This final deeming rule is a foundational rule that will provide many public health benefits, as described in the NPRM (79 FR 23142 at 23148 and 23149), and will provide FDA with critical information about the health risks of ENDS and other newly deemed products, including data from ingredient listing submissions and reporting of HPHCs required under the FD&C Act. Also, once this rule becomes effective, newly deemed products may be subject to additional regulations. For example, FDA has the authority under section 906(e) of the FD&C Act to issue a rule establishing tobacco product manufacturing practices, and this authority applies to deemed products. FDA also has the authority under section 907 of the FD&C Act to establish product standards for deemed products, including requirements with respect to packaging. The Agency issued an ANPRM prior to this deeming rule, seeking comments, data, research, or other information that may inform regulatory actions FDA might take with respect to nicotine exposure warnings and the use of child-resistant packaging. In addition, elsewhere in this issue of the **Federal Register,** FDA has made available a draft guidance for public comment, which when final will describe FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products, including recommendations for nicotine exposure warnings and child-resistant packaging that would help to support a showing that the marketing of a product is appropriate for the protection of the public health.

(Comment 152) Some comments stated that e-cigarettes should be subject to little or no FDA regulation, because e-cigarettes inhibit withdrawal symptoms in users with a history of relapse (Ref. 191) and lead to reduction and cessation in asthmatic smokers (Ref. 107).

(Response) FDA disagrees. Although ENDS may potentially provide cessation benefits to individual smokers, no ENDS have been approved as effective cessation aids. If an ENDS manufacturer wishes to make a cessation claim, the company must submit an application for their ENDS to be marketed as a medical product.

G. Modified Risk Claims

In the NPRM, FDA noted that it expects public health benefits through the application of section 911 of the FD&C Act to the newly deemed tobacco products. Historically, certain users have initiated and continued using certain tobacco products based on unauthorized modified risk claims and consumers' unsubstantiated beliefs. Application of section 911 will prohibit the introduction into interstate commerce of MRTPs unless FDA issues an order permitting their marketing.

(Comment 153) A few comments expressed concern that imposition of section 911 of the FD&C Act will force e-cigarette manufacturers to implicitly lie by not permitting them to tell consumers that their products are safer alternatives to conventional cigarettes, to advertise that they do not contain tobacco, and to state that they are "smoke free." They added that the public already overwhelmingly believes that e-cigarettes are reduced risk products and, therefore, the section 911 requirements are irrelevant (Refs. 178, 192). However, other comments stated that manufacturers should be prohibited from making cessation claims without providing scientific evidence to support their efficacy as a cessation mechanism.

(Response) FDA disagrees with concerns that ENDS manufacturers will not be able to make claims that properly represent their products. Section 911 is one of the provisions of the statute that applies automatically to deemed products. It was included in the FD&C Act to protect consumers from manufacturers making invalid or unsubstantiated claims, as many had done with respect to their designation of cigarettes as "light," "low," or "mild." The mistaken belief that "light" and "low-tar" cigarettes were safer than other cigarettes prompted many smokers to switch to such products instead of quitting altogether. Section 911 will prevent consumers from being similarly misled by ensuring a manufacturer may not make unsubstantiated claims. Manufacturers that have data to substantiate modified risk claims for a particular product can submit an MRTP application so that FDA can determine that the product meets the statutory standard and can issue an order authorizing it to be marketed as an MRTP.

As Congress recognized,

> [u]nless tobacco products that purport to reduce the risks to the public of tobacco use actually reduce such risks, those products can cause substantial harm to the public health to the extent that the individuals, who would otherwise not consume tobacco products or would consume such products less, use tobacco products purporting to reduce risk. Those who use products sold or distributed as modified risk products that do not in fact reduce risk, rather than quitting or reducing their use of tobacco products, have a substantially increased likelihood of suffering disability and premature death. The costs to society of the widespread use of products sold or distributed as modified risk products that do not in fact reduce risk or that increase risk include thousands of unnecessary deaths and injuries and huge costs to our health care system.

(section 2(37) of the Tobacco Control Act).

(Comment 154) Some comments believed that e-cigarettes should only be authorized as MRTPs, rather than new tobacco products via the PMTA or SE pathways, because that would allow them to meet the predominant expectations of consumers.

(Response) FDA disagrees. The Tobacco Control Act requires all new tobacco products, including MRTPs, to go through premarket review and obtain a marketing authorization order via the PMTA, SE., or SE exemption pathways. A manufacturer who wants to sell a product for use to reduce harm or risk of tobacco-related disease can also obtain authorization to market an MRTP if the manufacturer submits an application under section 911 of the FD&C Act and FDA issues such an order.

(Comment 155) A comment suggested that to address unauthorized modified risk claims, we add the following language to the final rule: No vapor product or alternative nicotine product shall be considered to be "sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products" solely because its label, labeling, or advertising uses the following phrases to describe such product and its use: "not consumed by smoking," "does not produce smoke," "smokefree," "without smoke," "no smoke," or "not smoke."

(Response) Section 911 of the FD&C Act requires FDA to assess MRTP claims for specific products. Therefore, FDA will evaluate products on a case-by-case basis to determine whether they are "sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco product" as stated in section 911. However, we note that e-cigarettes and similar ENDS products are not "smokeless" products, as the user is inhaling constituents (which are different from a smokeless tobacco product, as defined in the Tobacco Control Act). In addition, FDA is aware that some ENDS might heat their product to a level high enough to cause combustion.

(Comment 156) Many comments stated that the NPRM may promote conventional tobacco use because e-cigarette manufacturers will be unable to inform smokers that their products are safer alternatives or that they do not contain tobacco. They believed the NPRM weakens the impact that the e-cigarette industry might otherwise exert on the tobacco industry.

(Response) FDA disagrees. First, this final rule does not prohibit ENDS manufacturers from making claims that they are safer than conventional tobacco products if they can provide evidence to satisfy the requirements and obtain marketing authorization from FDA under section 911 of the FD&C Act. Second, FDA believes that ENDS could serve as alternatives to combusted tobacco products.

H. Dual and Polytobacco Use

In the NPRM, FDA noted its concerns that adult consumers may use one or more of the proposed deemed products in conjunction with cigarettes or other tobacco products. FDA also noted that studies suggest that some noncigarette tobacco users may go on to become addicted cigarette smokers (79 FR 23142 at 23159).

It is also recognized that some dual users of ENDS and cigarettes may be transitioning away from combustible tobacco use and that such transient periods of dual use may not present greater health risks than that observed during sole use of combustible tobacco. In a peer-reviewed study published recently in *Cancer Prevention Research,* investigators evaluated users of a single brand of "cig-a-like" ENDS and found that both cigarette smokers who switched to using the evaluated ENDS products and those who switched to dual use of the evaluated ENDS and cigarettes all demonstrated significant reductions in exposure to carbon monoxide and the toxicant acrolein (Ref. 194).

(Comment 157) Many comments expressed concern that the rate of dual use of e-cigarettes and combusted tobacco products is high, particularly among middle and high school students (Ref. 16). They stated that adolescents do not use e-cigarettes as cessation aids but rather use them in conjunction with conventional cigarettes (Ref. 193; see Ref. 194). They also indicated that this dual use and the fact that youth who experiment with e-cigarettes are 7.7 times more likely to become established smokers than those who do not experiment (Ref. 116) suggest that e-cigarette use leads to increased use of combusted tobacco products. However, they noted that we need long-term studies like FDA's PATH Study to confirm that assertion. Some comments also stated that cigarette smokers who use a second tobacco product even occasionally are at higher risk for continued tobacco use (Ref. 195).

Other comments believed that dual use should not be a concern, generally relying upon an Internet study of more than 19,000 e-cigarette users in which dual users had decreased from 20 to 4 cigarettes per day by the end of the study (Ref. 109). Some comments also expressed the belief that, because clinical studies show that e-cigarettes deliver only modest concentrations of nicotine to novice e-cigarettes users (Ref. 196), this would also be the case for nonsmoking youth and young adults and, therefore, would make the possibility of addiction less likely. Others argued that advanced e-cigarette products deliver nicotine more effectively, making adult consumers less likely to dual use or revert back to smoking. In addition, they claimed that if e-cigarettes were acting as a gateway to cigarette use, the current increase in e-cigarette use would lead to a corresponding increase in youth cigarette use (which has not occurred). In fact, they said an overlap of combusted tobacco and e-cigarette use is necessary if a tobacco user begins e-cigarette use to transition away from combusted tobacco consumption.

(Response) FDA is aware of dual use of ENDS and combusted tobacco products and is concerned about the potential impact of this practice on nicotine addiction and cessation. FDA also is concerned because this dual and polytobacco use pattern appears to be common among adolescents and young adults (Ref. 197). However, recent CDC NCHS data on young adult and adult use patterns of e-cigarettes indicate that former smokers and current smokers trying to quit are more likely to use e-cigarettes than former smokers who quit smoking more than 1 year ago and those who had never smoked (Ref. 24). These results indicate that dual use of tobacco may also be present during the transitional phase when smokers of combusted tobacco products are attempting to quit, which is also supported by personal stories included in the comments. In addition, the largest study to date in the EU found that e-cigarette use was more likely among smokers who had made a quit attempt during the past year as compared to those who never smoked (Ref. 109).

Other studies illustrate that current or former smokers have tried e-cigarettes not intending to quit tobacco use, but instead, because they are "Easy to use when I can't smoke" (Ref. 198) or can be used in places where conventional tobacco use is not allowed (Ref. 199). FDA remains committed to supporting long-term population-level research, such as the PATH Study, that will help elucidate reasons for and patterns in tobacco initiation, product switching, and dual use across the spectrum of tobacco products on the U.S. market, including ENDS and conventional cigarettes.

(Comment 158) Many comments noted that almost all e-cigarettes contain nicotine (Ref. 192). This nicotine delivery varies within and across brands (Refs. 200, 201) and by the user's level of experience with these products (*e.g.,* Ref. 202). While many comments expressed minimal concerns about abuse liability of e-cigarettes, believing that users will eventually switch entirely to e-cigarettes, others expressed the belief that long-term use of e-cigarettes may lead to addiction in youth and young adults.

(Response) FDA shares similar concerns that youth may initiate tobacco use with ENDS, become addicted, and then dual use or move on to traditional tobacco products. FDA discussed available data regarding dual and polytobacco use in the NPRM and is unaware of long-term studies finding that dual or polytobacco users eventually switch to using just one tobacco product (79 FR 23142 at 23159 and 23160). However, findings from a recent study of 694 participants aged 16 to 26 years old suggest that youth e-cigarette users might transition to smoking traditional cigarettes (Ref. 203). Therefore, FDA remains concerned that youth may use one of the newly deemed products, whether it be an ENDS or any other tobacco product, and dual use with other tobacco products in the future.

(Comment 159) Some comments urged FDA to evaluate e-cigarettes based on their scientific merit and contribution to public health. At least one comment felt that certain researchers in the tobacco field were biased based on their connections to public health advocates or what the comment refers to as "big tobacco companies." Some comments stated that FDA only considered journal articles when it should have considered other available information.

(Response) FDA uses the best evidence available from peer reviewed journals and other reputable sources to support this rule and fulfill our public health mandate. In the context of rulemaking, FDA follows the requirements of Executive Orders 12866 and 13563 by basing its decisions "on the best reasonably obtainable scientific, technical, economic and other information." As stated in the NPRM, we will continue to fund research to help us determine the public health impacts of ENDS. Long-term studies are not available to conclude that ENDS are a proven cessation product or to establish what effect e-cigarettes have on users who might otherwise quit but instead engage in dual use of ENDS and other tobacco products (79 FR 23142 at 23152).

I. Applicability of Section 901

In the preamble to the NPRM, FDA stated that the rule applies to all products that meet the definition of "tobacco product" under section 201(rr) of the FD&C Act and any future products that meet the definition. FDA stated that e-cigarettes meet the definition of "tobacco product."

(Comment 160) Many comments seeking to exclude e-cigarette products from the scope of the deeming rule stated that Congress only meant for FDA to regulate products with the greatest threat (*i.e.*, cigarettes and smokeless tobacco products). They stated that regulating all tobacco products as strictly as cigarettes are regulated is not warranted and that the rigid application of the Tobacco Control Act is not consistent with public health objectives.

(Response) FDA disagrees. Congress gave FDA immediate authority over certain tobacco products (*i.e.*, cigarettes, smokeless tobacco, cigarette tobacco, and roll-your-own tobacco) and the authority to deem other products (including ENDS and other products that meet the statutory definition of "tobacco product"). All tobacco products, regardless of the category of products, pose a health risk. Further, at this time, only some of the restrictions in part 1140 (which, prior to the rule, applied only to cigarettes and smokeless tobacco) will apply to the newly deemed products. Specifically, while the minimum age and identification, vending machine, and free sample provisions will apply to the newly deemed products, additional provisions in part 1140 (including minimum pack size and restrictions on self-service displays, sale and distribution of nontobacco items, and sponsorship of events) will not apply to the newly deemed products at this time.

(Comment 161) Many comments expressed concern that Congress did not wish to effectively ban e-cigarettes (as they claimed would occur as a result of deeming these products), because such a ban violates section 907(d)(3) of the FD&C Act. They stated that if Congress wanted to ban them, they would have done so under their drug authority.

(Response) FDA is not banning any category of tobacco product by issuing this final deeming rule.

(Comment 162) Many comments claimed that Congress did not intend for FDA to strictly apply the Tobacco Control Act requirements to all newly deemed products, especially those that do not contain tobacco leaf. They believed because e-liquids do not contain tobacco leaf, such products should be regulated differently than cigarettes and traditional smokeless tobacco products.

(Response) With this rule, FDA is deeming all products that meet the definition of "tobacco product," including e-liquids, to be subject to the tobacco product authorities in chapter IX of the FD&C Act, to address the public health concerns associated with them. The FD&C Act does not include any requirement that a product contain "tobacco leaf" to meet the definition of "tobacco product" and be deemed under this final rule. As stated previously, FDA is not requiring that ENDS and the other newly deemed products comply with all of the requirements of part 1140 at this time.

(Comment 163) Some comments suggested that we need more toxicological, epidemiological, and behavioral studies before deeming e-cigarettes under section 901. Other comments stated that FDA must regulate e-cigarettes despite not having the level of scientific evidence that is available for most conventional tobacco products.

(Response) FDA continues to research and fund studies regarding ENDS initiation, use (including transitions to other tobacco products and multiple use), perceptions, dependence, and toxicity (Ref. 195). FDA also has been conducting a series of public workshops to obtain additional information on e-cigarettes and their impact on public health (79 FR 55815). These workshops are not necessary to inform this deeming rule; however, they may inform FDA's development of future rules impacting ENDS. Any additional regulations regarding ENDS will be subject to the requirements of the APA.

(Comment 164) Some comments sought clarification as to FDA's authority over e-liquids that do not contain nicotine or other chemicals derived from tobacco plants and those e-liquids that contain nicotine derived from a nontobacco source (*e.g.*, eggplants or tomatoes). Others claimed that FDA does not have regulatory authority over e-cigarettes that are refillable and do not contain nicotine, but does have authority over e-liquids if the liquid contains nicotine. Yet, some said that e-liquids used in e-cigarettes should have an entirely new classification, because use of the words "tobacco product" in marketing materials would cause undue confusion for consumers.

(Response) As stated in section 201(rr) of the FD&C Act, the definition of "tobacco product" includes any product made or derived from tobacco, including any component, part, or accessory of a tobacco product. An e-liquid made or derived from tobacco meets this definition and, therefore, is subject to FDA's chapter IX authorities. E-liquids that do not contain nicotine or other substances derived from tobacco may still be components or parts and, therefore, subject to FDA's tobacco control authorities, if they are an assembly of materials intended or reasonably expected to be used with or for the human consumption of a tobacco product and do not meet the definition of accessory.

(Comment 165) Some comments tried to compare pipes and rolling papers (which are required to smoke tobacco) with e-cigarettes (which are required to "vape" e-liquids), stating that e-cigarettes should not be regulated. They indicated that, unlike rolling paper which is "intended for human consumption" and therefore a tobacco product component, a pipe is "non-consumable" and should not be considered a tobacco product component. They said that, like pipes, e-cigarettes are "non-consumable products" and, therefore, are not components or parts of tobacco products and not subject to regulation. They also stated that only the e-liquid is the consumable product and should be the only part of the e-cigarette subject to regulation.

(Response) The definition of "tobacco product" as set forth in section 201(rr) of the FD&C Act includes all components, parts, and accessories of tobacco products (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). FDA interprets components and parts of a tobacco product to include any assembly of materials intended or reasonably expected: (1) To alter or affect the tobacco product's performance, composition, constituents or characteristics; or (2) to be used with or for the human consumption of a tobacco product. Both e-cigarettes and pipes meet this definition. Thus, such products are subject to FDA's chapter IX authorities as a result of this rule.

(Comment 166) Many comments stated that FDA lacks any type of meaningful justification for deeming e-cigarettes because e-cigarettes do not represent the same level of public health threat as cigarettes. They claimed that FDA has the burden of showing a rational basis for regulation and that the lack of data showing that these products do not cause harm cannot serve as a basis for regulating them. In addition, some comments stated that FDA has no justification for regulating products simply because they may deliver nicotine. They likened such authority to imposing onerous regulations on caffeine, another plant-derived chemical.

(Response) FDA disagrees. FDA is deeming these products to address public health concerns (79 FR 23142 at 23148 and 23149). ENDS are tobacco products. As stated throughout this document, FDA has determined that deeming all products meeting the statutory definition of "tobacco product" will significantly benefit public health. We also note that by merely deeming ENDS to be tobacco products, FDA is not imposing the same level of regulation as is currently imposed on cigarettes. For example, restrictions on self-service displays, sale and distribution of nontobacco items, and sponsorship of events will not apply to ENDS at this time. FDA will consider the health effects of all products before determining whether to issue additional regulations.

(Comment 167) Many comments stated that the NPRM would ban virtually all of the e-liquid products and premium vaporizers (including mods, tanks, and open systems) and other components or parts because manufacturers of such products would not have adequate resources to comply with the requirements of the law.

(Response) FDA disagrees. FDA is not banning *any* tobacco product under this final rule. Rather, FDA is extending its authority to regulate such products under section 901 of the FD&C Act. Manufacturers of ENDS products were on notice that they could be considered FDA-regulated tobacco products since the enactment of the Tobacco Control Act and the issuance of the *Sottera* decision shortly thereafter. See section VIII.K for additional discussion regarding the *Sottera* case. Therefore, FDA disagrees with any comments referring to this rule as banning any categories of tobacco products.

(Comment 168) Some comments stated that FDA does not have the authority to regulate the ingredients that can be used in e-liquids.

(Response) FDA clarifies that, although it will not be directly regulating the individual ingredients in e-liquids at this time, sections 905 and 910 of the FD&C Act give FDA authority to review and consider ingredients in making determinations on SE reports and PMTAs (*i.e.*, the Agency will look at ingredients within a specific e-liquid and determine whether the overall tobacco product meets the statutory standard for marketing authorization). In addition, section 904 requires manufacturers to submit a listing of all ingredients added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand and by quantity in each brand and subbrand, and section 915 of the FD&C Act authorizes FDA to issue a regulation to require that "tobacco product manufacturers, packagers, or importers make disclosures relating to the results of the testing of tar and nicotine through labels or advertising or other appropriate means, and make disclosures regarding the results of the testing of other constituents, including smoke constituents, *ingredients*, or additives, that the Secretary determines should be disclosed to the public to protect the public health and will not mislead consumers about the risk of tobacco-related disease" (emphasis added).

(Comment 169) A few comments noted the differences among products in the ENDS category in contrast to the relatively uniform category of combusted tobacco products. Given these differences and the rapid cycle of innovation and product development for ENDS products, they stated that FDA cannot use the Tobacco Control Act framework to regulate them.

(Response) FDA agrees that there are many differences among the products in the ENDS category. However, there are many differences among combusted tobacco products as well. For example, many cigars are wrapped in whole tobacco leaf, whereas cigarettes are not. Waterpipe tobacco is consumed in a manner very different from the consumption of cigarettes and cigars. The differences among these products do not affect the Agency's ability to regulate them in accordance with the requirements of the Tobacco Control Act.

J. Definitions

Several comments suggested that we add definitions specific to e-cigarettes and their components and parts. Comments stressed the importance of defining terms broadly enough to ensure all manufacturers of the finished products or components and parts of the finished products are covered by the definitions.

(Comment 170) Some comments suggested that FDA clearly identify nomenclature and constituents of ENDS products because ENDS is a much broader category than e-cigarettes. Similarly, some comments stated that not defining these products would fail to address the exploding market of e-cigarettes and their e-cigarette components and parts. They also stated that an ENDS definition is necessary so State and local governments can use consistent definitions.

(Response) FDA agrees that there is an expanding market of tobacco products that meet the FD&C Act definition of "tobacco products." However, FDA does not believe it is necessary to define individual categories of tobacco products for purposes of this rule. In fact, by deeming "tobacco products" generally, it will help ensure that novel and future tobacco products are introduced into the market in an appropriate and efficient manner. FDA may issue specific definitions at a later time if it determines that doing so is appropriate.

(Comment 171) At least one comment recommended that we establish a definition of "vapor product" and define it as "any noncombustible tobacco-derived product containing nicotine that employs a heating element, power source, electronic circuit, or other electronic, chemical or mechanical means, regardless of shape or size, including any component thereof, that can be used to produce vapor from nicotine in a solution or other form." The comment stated that several States have adopted variations of this definition and that it would provide necessary clarity.

Likewise, at least one comment suggested that we establish a definition of "alternative nicotine product," which would be defined as "any noncombustible tobacco-derived product containing nicotine that is intended for human consumption, whether chewed, absorbed, dissolved or ingested by any other means." The comment stated that several States have adopted variations of this definition and that it would provide necessary clarity.

(Response) For the reasons explained previously, FDA finds that it is not necessary to add these definitions to the codified for this final rule.

(Comment 172) A few comments suggested that FDA clarify the differences between "liquid nicotine" and "e-cigarette liquid (or e-liquid)." They noted that, throughout the NPRM, FDA referred to the liquid component of e-cigarettes as "e-cigarette liquid," which contains nicotine, flavorings, and other ingredients. However, in a few instances, FDA referred to "nicotine solutions" or "nicotine liquids." They asked that we clarify the difference to avoid confusion and unintended coverage under chapter IX of the FD&C Act.

(Response) FDA agrees that clarification is necessary. Liquid nicotine does not have flavorings or other ingredients added to it. E-cigarette liquid (or "e-liquid") is a liquid containing nicotine, flavorings, and/or other ingredients. This final rule regulates e-liquid and liquid nicotine that is made or derived from tobacco.

(Comment 173) Some comments requested that FDA refer to ENDS products as vapor products and use definitions that differentiate between the products that use combustion and those that use vaporization. They stated that this distinction is necessary because the potential harms posed by these products are different and consumers may believe that vapor products are as dangerous as combusted smoking products. One comment provided an example as to how to recategorize tobacco products based on their delivery method and combustion. Another comment requested that FDA add "combustion" to the current definition of cigarette to differentiate between combusted and vaporized products.

(Response) For purposes of this deeming regulation, FDA does not believe it is necessary to distinguish between vapor products and combusted products. The statutory definition of "cigarette" was established by Congress and describes conventional cigarettes (section 900(3) of the FD&C Act). If FDA finds reason to differentiate between the combusted and vaporized products for the purpose of future regulations, FDA will issue a new NPRM to propose such definitions. In addition, FDA is aware that some e-cigarettes are heated to a high enough level to cause combustion of the e-liquid.

(Comment 174) At least one comment suggested that FDA alleviate any potential confusion between conventional cigarettes and e-cigarettes by adding a third subsection to the proposed definition of "cigarette" to read as follows: " 'Cigarette' (1) Means a product that: (i) Is a tobacco product and (ii) meets the definition of the term "cigarette" in section 3(1) of the Federal Cigarette Labeling and Advertising Act; (2) includes tobacco, in any form, that is functional in the product, which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette or as roll-your-own tobacco; and (3) does not include a product such as nicotine [or products containing nicotine] that is derived from tobacco but does not contain tobacco."

(Response) FDA finds that this addition to the cigarette definition is unnecessary to prevent confusion between the two product categories. The definition of "cigarette" in § 1140.3 of this final rule conforms to the definition in section 900(3) of the FD&C Act.

(Comment 175) One comment requested that FDA establish one common name for all vapor products, so the manufacturers, distributers, importers, and retailers of these products can comply with section 903(a)(4) of the FD&C Act, which requires that the manufacturer include an established name on the product labeling.

(Response) At this time, FDA has not established a common nomenclature for this group of products. FDA will consider these comments in determining whether future regulatory action is appropriate.

K. Sottera Decision

In the NPRM, FDA explained that, as set forth in the *Sottera* decision, e-cigarettes that are "customarily marketed" are tobacco products over which the Agency cannot exercise its tobacco product authority until it finalizes a regulation that deems them to be subject to chapter IX of the FD&C Act.

(Comment 176) Some comments provided analysis of the D.C. Circuit's decision in *Sottera, Inc.* v. *Food and Drug Administration,* 627 F.3d 891 (D.C. Cir. 2010), which formed part of the basis for FDA's decision to deem "tobacco products" subject to FDA's tobacco product authorities. They took issue with FDA's description of the key points of the case, stating that FDA is misreading the holding of *Sottera* to conclude that the court there held that FDA has jurisdiction over e-cigarettes as tobacco products because that question was not presented in the case.

(Response) FDA's analysis of the *Sottera* decision in the proposed deeming rule (79 FR 23142 at 23149 and 23150) was correct. On December 7, 2010, the D.C. Circuit held that FDA has the authority to regulate customarily marketed tobacco products under the Tobacco Control Act and products made or derived from tobacco that are marketed for a therapeutic purpose under the medical product provisions of the FD&C Act. (See *Sottera, Inc.* v. *Food & Drug Administration,* 627 F.3d 891 (D.C. Cir. 2010).) On January 24, 2011, the D.C. Circuit denied the government's petitions for rehearing and rehearing *en banc* (by the full court). (See *Sottera, Inc.* v. *FDA,* No. 10–5032 (D.C. Cir. Jan. 24, 2011) (*per curiam*).) On April 25, 2011, FDA issued a letter to stakeholders indicating its intent to deem additional tobacco products, including e-cigarettes, to be subject to FDA's authorities in chapter IX of the FD&C Act.

(Comment 177) A few comments claimed that FDA had attempted to ban e-cigarettes, the *Sottera* decision established the legality of e-cigarettes, and FDA's purported ban was unlawful.

(Response) FDA disagrees. Prior to the *Sottera* case, FDA did not seek to ban e-cigarettes. Instead, FDA had detained several shipments of e-cigarettes and their accessories offered for import by Smoking Everywhere and Sottera, Inc. (doing business as NJOY) and eventually refused admission into the United States to two of Smoking Everywhere's shipments on the ground that the products appeared to be unapproved drug/device combination products. FDA did not attempt to categorically ban e-cigarettes for sale in the United States but, instead, sought to regulate them under its drug/device authorities.

(Comment 178) A few comments stated that manufacturers are marketing e-cigarettes as cessation products and, therefore, they should be regulated as cessation products.

(Response) As stated in the D.C. Circuit's decision in *Sottera,* e-cigarettes that are customarily marketed tobacco products are subject to FDA's tobacco product authorities. If an e-cigarette manufacturer wishes to market its product for a therapeutic purpose, the company would be subject to FDA's drug/device authorities and must submit an application to be marketed as a medical product.

IX. Effect of Deeming Rule on Vape Shop Manufacturers

Some comments requested clarification regarding the regulatory status of an ENDS retail establishment that sells e-liquids (sometimes known as a vape shop). Such establishments sell a variety of products including ENDS, replacement pieces, hardware, custom mixed e-liquids, and other related accessories.

If an establishment mixes or prepares e-liquids or creates or modifies aerosolizing apparatus for direct sale to consumers for use in ENDS, the establishment fits within the definition of "tobacco product manufacturer" in section 900(20) of the FD&C Act and the combinations it mixes and/or prepares are new tobacco products within the meaning of section 910(a)(1). For requirements not covered by the compliance policy set forth in this section, ENDS retail establishments that meet the definition of a manufacturer should refer to the compliance periods in tables 2 and 3. As discussed in the Analysis of Impacts (Ref. 204), FDA expects that most vape shops will stop mixing e-liquids (and preparing other new tobacco products) to avoid being "manufacturers" under the Tobacco Control Act.

The definition of "tobacco product manufacturer" in section 900(20) includes "any person, including any repacker or relabeler, who manufactures, fabricates, assembles, processes, or labels a tobacco product." Additionally, for purposes of section 905, the FD&C Act defines "manufacturing, preparation, compounding, or processing" to include "repackaging, or otherwise changing the container, wrapper or labeling of any tobacco product package from the original place of manufacture to the person who makes the final delivery or sale to the ultimate consumer or user." Section 910(a)(1) defines a "new tobacco product" as "any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007." Therefore, establishments engaged in mixing or preparing e-liquids or creating or modifying aerosolizing apparatus for direct sale to consumers for use in ENDS are tobacco product manufacturers and, consequently, are subject to all of the statutory and regulatory requirements applicable to manufacturers.

The statute authorizes FDA to regulate the manufacture of all new products, including those manufactured at the retail level. This is important to FDA's ability to protect the public health since products manufactured at the retail level pose many of the same public health risks as those manufactured upstream and possibly additional risks related to the lack of standard manufacturing practices and controls. The introduction of statutory controls and oversight into a historically unregulated market inevitably will lead to some market change and consolidation. FDA recognizes that, with the implementation of this final rule, vape shops that meet the definition of tobacco product manufacturer may cease engaging in manufacturing activities rather than comply with requirements for manufacturers under this final rule. However, FDA notes that such entities will have the option to continue operating solely as retailers, as some vape shops currently do. In addition, as noted earlier, FDA believes that this policy (and the deeming rule as a whole) will not stifle innovation but could, instead, encourage it. Over time, FDA expects that its premarket review authorities will spur creative evolution and help to create a market where available products present a lower risk of user and population harm, provide a more consistent delivery under varying conditions of use, are less likely to lead to initiation of tobacco use, and/or are easier to quit. In recent years, ENDS products have proliferated in the absence of regulation, in some cases resulting in a lack of quality control and consistency, consumer confusion and even availability of acutely toxic products. In this context, we expect that changes in the market in response to regulation will have significant benefits for public health and will be a net benefit overall.

As the ENDS market continues to evolve, it is important that FDA exercise its authority to oversee all establishments engaged in manufacturing activities and their products, in order to protect consumers and to carry out the public health objectives of the Tobacco Control Act.

A. Premarket Requirements (Sections 905 and 910)

As stated throughout the document, manufacturers of newly deemed products that are not grandfathered will be required to obtain premarket authorization of their products through one of three pathways—PMTA, SE or SE exemption (sections 905 and 910 of the FD&C Act). Therefore, ENDS retailers engaged in mixing or preparing e-liquids or creating or modifying aerosolizing apparatus will be required to obtain premarket authorization for each non-grandfathered product that they prepare for sale or distribution to consumers. However, under the compliance policy laid out in section V.A, FDA does not intend to enforce, during specified compliance periods, the premarket review requirements including for ENDS retailers that mix or prepare the same e-liquids they have been preparing and offering for sale as of the effective daterule, or that create or modify aerosolizing apparatus resulting in the same products they have been creating as of the effective date. An initial compliance period, the length of which is dependent on the type of application to be submitted, is intended to provide additional time to prepare and submit premarket applications. In addition, for the 12 months following this initial compliance period, FDA intends to continue the compliance policy and does not intend to enforce the premarket review requirements if the firm has a pending submission. This means that, during this 12-month continued compliance period of FDA review, FDA expects that ENDS retailers of any kind will sell only those products that are (1) grandfathered; (2) authorized by FDA; or (3) tobacco products for which the ENDS retailer or another (upstream) manufacturer has submitted a marketing application/submission to FDA during the initial compliance period. (For PMTAs, the initial compliance period to submit is 24 months after the final rule effective date.)

FDA expects that this 12-month continued compliance period of FDA review will benefit manufacturers and retailers of newly deemed products, including ENDS retailers, since upstream manufacturers that submit applications will have a significant incentive to make retailers aware of their pending applications/submissions. Specifically, we expect that upstream manufacturer suppliers will inform ENDS retailers selling their products whether the upstream manufacturer has submitted a premarket application for such e-liquids and other ENDS products within the initial compliance period such that the retailers can benefit from the continued compliance period while FDA reviews such applications. FDA expects that manufacturers will have an incentive to make retailers aware of which products are the subject of applications, which will enable retailers to know whether a marketing application has been submitted and whether FDA has acted on an application. In addition, retailers may contact suppliers for relevant product information. Therefore, after 36 months from the effective date (*i.e.*, at the end of the initial compliance period plus 12-month continued compliance period), FDA expects that all ENDS retailers will sell only those products that are either grandfathered or for which they have, or an upstream supplier has, received premarket authorization.

TABLE 4—COMPLIANCE POLICY FOR PREMARKET REQUIREMENTS—ENDS RETAIL ESTABLISHMENTS

0–24 months after the rule goes into effect	24–36 months after the rule goes into effect	Beyond 36 months after the rule goes into effect
FDA does not intend to enforce premarket authorization requirements for e-liquid products that retailers mix and sell without marketing authorization, provided that final mixture is the same as a product the retailer was selling or offered for sale as of the effective date.	FDA does not intend to initiate enforcement action for e-liquid products that retailers mix and sell where a marketing application has been submitted and is still pending for the final mixture.	The compliance period no longer applies, even if the final mixture has a pending marketing submission/application. All products for which a marketing submission/application is pending are subject to enforcement action.

As stated previously, because products manufactured at the retail level pose many of the same public health risks as those manufactured upstream, and possibly additional risks, it is important to enforce the statutory requirements for all new products, even those currently manufactured by ENDS retailers.

In general, the FD&C Act provides three pathways that manufacturers may use to seek market authorization for a new product: The premarket tobacco product application pathway, the SE pathway, and the exemption from SE pathway. FDA anticipates that most manufacturers of e-liquids and apparatus components/complete delivery systems will seek authorization through the PMTA pathway. To obtain marketing authorization under the PMTA pathway, manufacturers are required to establish, among other things, that permitting their product to be marketed would be appropriate for the protection of the public health. In establishing this, manufacturers should take into account, and FDA will consider, the ways in which the new product is likely to be used. For example, PMTAs for these products should contain information on whether the product is likely to be used alone or together with other legally marketed tobacco products (such as available delivery systems), as well as the type and range of the other products with which it is likely to be used.

While the statutory standard will apply to all products for which a PMTA is filed, FDA expects that different classes of products may have differing likelihoods of success in meeting the standard, by virtue of their expected use. As stated previously, to meet the statutory standard, PMTAs should contain information on whether a product is likely to be used alone or together with other legally marketed products and the public health implications of those likely uses. FDA has issued a draft guidance on PMTAs for ENDS, published concurrently with this final rule, which, when finalized, will explain FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed e-liquids and hardware/apparatus components. FDA intends to act as expeditiously as possible with respect to all new applications, while ensuring that statutory standards are met.

To reduce research burdens and increase efficiency for ENDS retail establishments that file applications, FDA suggests that ENDS retail establishments use master files whenever possible. By obtaining permission from a master file holder, manufacturers could reference extensive ingredients lists and constituent testing that they otherwise would be required to perform themselves for marketing authorization. To facilitate this process, elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a final guidance to provide information on how to establish and reference a TPMF. This information will help applicants of newly deemed products prepare premarket and other regulatory submissions because they can reference information in TPMFs rather than develop the information on their own.

Given the anticipated availability and use of master files (as discussed in a separate, final guidance published concurrent with Deeming), which allows manufacturers to rely on the data and analysis submitted to FDA by separate entities, FDA anticipates that manufacturers will, over time, benefit from significantly increased efficiencies and reduced costs for complying with the statute. Such a system prevents and reduces duplication and allows for manufacturer reliance on confidential or sensitive non-public information while maintaining its confidentiality, thus saving time and reducing burdens for multiple manufacturers. Because of the nature of upstream supply of many components for ENDS products, especially e-liquids, FDA anticipates that commercial incentives will be sufficient to drive manufacturer reliance on the system of master files. We also note that at present, FDA understands that, based on the Agency's review of publically available information as discussed in section III.C of the Analysis of Impacts (Ref. 204), the number of entities engaged in upstream production of liquid nicotine and flavors specifically developed for use with e-liquids is small, in the range of seven to thirteen entities (see earlier discussion in response to comment 34). Given the current marketplace, the master file system is likely to prove widely appealing and widely utilized by the ENDS industry, reducing burden significantly.

In addition, FDA intends to open public dockets for uniquely identified compounds likely to be used in an e-liquid product, such as propylene glycol, glycerin, nicotine, colorants, and flavoring agents. FDA intends to invite stakeholders to submit to the docket information regarding specific compounds, including data, studies, or other files, such as data on individual health effects of inhalation exposure, animal study data examining exposure to varying levels of compounds within e-liquids, or testing the impact of temperature on changes to the aerosol constituents. This information could then be used to help support applications for premarket review, for example, generating information on HPHCs in ENDS products that is then submitted as part of a PMTA.

B. Ingredient Listing and HPHC Requirements (Section 904 and 915)

As of the effective date of this rule, the ingredient listing requirements of section 904 of the FD&C Act will apply to manufacturers of the newly deemed products, including ENDS retail establishments that mix or prepare e-liquids or create or modify aerosolizing apparatus for sale or distribution. At this time, FDA intends to limit enforcement to finished tobacco products. FDA does not at this time intend to enforce these requirements for manufacturers of components and parts of newly deemed products that are sold or distributed solely for further manufacturing into finished tobacco products. This means that FDA generally intends to enforce these requirements with respect to ENDS retail establishments that mix or prepare e-liquids or create or modify aerosolizing apparatus for sale or distribution directly to consumers but not to distributors who sell components for further manufacturing. However, if the upstream distributor submits an ingredient list for a particular product, FDA does not intend to enforce the ingredient listing requirement against an ENDS retailer with respect to that particular product. We note that FDA also intends to issue a guidance regarding HPHC reporting under section 904(a)(3), and later a testing regulation as required by section 915, with enough time for manufacturers to report given the 3-year compliance period for HPHC reporting. Section 904 (a)(3) requires the submission of a report listing all constituents, including smoke constituents, identified as harmful or potentially harmful (HPHC) by the Secretary. Section 915 requires the testing and reporting of the constituents, ingredients, and additives the Secretary determines should be tested to protect the public health. The section 915 testing and reporting requirements apply only after FDA issues a regulation implementing that section, which it has not yet done. Until these testing and reporting requirements have been established, newly deemed tobacco products (and currently regulated tobacco products) are not subject to the testing and reporting provisions found under section 915. As noted elsewhere in this document, FDA does not intend to enforce the reporting requirements under section 904(a)(3) for newly deemed products before the close of the 3-year compliance period, even if the HPHC guidance and the section 915 regulation are issued well in advance of that time.

C. Registration and Product Listing (Section 905)

Section 905 of the FD&C Act requires every person who owns or operates an establishment engaged in the "manufacture, preparation, compounding, or processing of a tobacco product" to register its establishment with FDA and submit a listing of its tobacco products to the Agency. If an ENDS retail establishment engages in these activities, section 905 requires the establishment to register and list its products with FDA in accordance with this section. These requirements apply under the statute for all distinct products manufactured, and they enable FDA to assess the landscape of products manufactured by these entities. If ENDS retail establishments are mixing or preparing e-liquids or creating or modifying aerosolizing apparatus for direct sale to consumers, then they will have to list each e-liquid combination that they sell. It will be the responsibility of the ENDS retail establishment, as a manufacturer, to determine how many and which products they plan to manufacture. For shops that prepare an expansive array of custom mixes, with many gradations of flavor, nicotine strength or other characteristic, this would mean identifying, listing, and reporting ingredients for a large number of distinct products. In reality, however, we expect that such entities will elect to narrow the list of combinations they sell (with more limited distinctions in strength and flavor, etc.), since such a narrowing will allow them to continue providing custom products and a variety of options while simplifying their reporting. However, since the time and cost of listing each additional mixture is expected to be very low, the reduction will not necessarily be significant. In addition, any narrowing may reflect a reduction in products that are listed but are not actually sold.

D. Tobacco Health Document Submissions (Section 904)

Section 904(a)(4) of the FD&C Act requires each tobacco product manufacturer or importer, or agent thereof, to submit all documents that relate to health, toxicological, behavioral, or physiologic effects of current or future products, their constituents (including smoke constituents), ingredients, components, and additives. As discussed in section IV.D (discussing the compliance policy for small-scale tobacco product manufacturers), FDA, for an additional 6 months following the end of the generally applicable compliance period, does not intend to enforce against those small-scale tobacco product manufacturers (including ENDS retail establishments) who submit the required information.

E. Office of Small Business Assistance

Under section 901(f) of the FD&C Act, one of FDA's initial activities upon passage of the Tobacco Control Act was to establish the OSBA within CTP to assist small tobacco product manufacturers and retailers in complying with the law. FDA recognizes that the issuance of this final deeming rule, including the clarifying information noting that ENDS retail establishments are manufacturers subject to this rule, may result in many additional small tobacco product entities contacting OSBA for assistance. Accordingly, FDA intends to hire additional OSBA staff to provide assistance to small tobacco product entities wherever possible.

X. Regulation of Other Categories of Products

FDA is finalizing this rule to deem all products that meet the definition of tobacco product in section 201(rr) of the FD&C Act (except accessories of newly deemed tobacco products) to be subject to FDA's tobacco product authorities. In addition, as stated in the NPRM, any future tobacco product that meets the definition in section 201(rr) (except accessories of newly deemed tobacco products) will also be subject to FDA's authorities under chapter IX of the FD&C Act. Regulation of the newly deemed tobacco products is intended to address the public health concerns related to these products. A summary of the comments regarding dissolvables, gels, pipe tobacco, waterpipe tobacco, other alternative products, and future tobacco products is discussed as follows. FDA's responses to the comments are also included.

A. Nicotine in Newly Deemed Products

Comments were split as to the health risks of nicotine and its impact on adult tobacco product users.

(Comment 179) Many comments stated that nicotine is addictive, and all products containing nicotine pose a health threat to youth. Some also stated that nicotine can have detrimental effects on the cardiovascular system and promotes lung carcinomas (Refs. 15, 205). Other comments noted that it is generally accepted that nicotine is not directly responsible for tobacco-related death and disease (Ref. 206) and that the Surgeon General has stated that it is the toxic substances in tobacco products (not the nicotine) that cause almost all tobacco-related death and disease (Ref. 9).

(Response) FDA agrees that nicotine is the primary addictive substance in tobacco products, as stated in the proposed deeming rule (79 FR 23142 at 23180). The Surgeon General has long recognized that nicotine is the primary pharmacologic agent of tobacco that can be absorbed into the bloodstream and cause addiction (Ref. 1 at 6–9). In addition, the Surgeon General has stated that addiction to nicotine is the "fundamental reason that individuals persist in using tobacco products, and this persistent use contributes to many diseases" (Ref. 2 at 105). While nicotine does not directly cause most smoking-related diseases, addiction to the nicotine in tobacco products sustains tobacco use, leading to the ingestion of the toxic substances in combusted tobacco products and tobacco smoke (Ref. 14). However, nicotine, in low doses, is given in different routes of administration as nicotine replacement therapies to help consumers to stop smoking, when approved for such purposes.

While the inhalation of nicotine (*i.e.*, nicotine without the products of combustion) is of less risk to overall public health than the inhalation of nicotine delivered by smoke from combusted tobacco products, limited data suggests that the pharmacokinetic properties of inhaled nicotine can be similar to nicotine delivered by combusted tobacco products. Thus, inhaled nicotine from a non-combustible product may be as addictive as inhaled nicotine delivered by combusted tobacco products. Researchers recognize that the effects from nicotine exposure by inhalation are likely not responsible for the high prevalence of tobacco-related death and disease in this country (Refs. 10, 11). Although nicotine has not been shown to cause the chronic disease associated with tobacco use, the 2014 Surgeon General's report noted that there are risks associated with nicotine (Ref. 9 at 111). For example, nicotine at high enough doses has acute toxicity (id.). Nicotine exposure during fetal development has lasting adverse consequences for brain development (id.). Nicotine also adversely affects maternal and fetal health during pregnancy, contributing to multiple adverse outcomes such as preterm delivery and stillbirth (id.). Further, data in animal models suggest that nicotine exposure during adolescence may have lasting adverse consequences for brain development (id.). Some studies also have found that nicotine can have detrimental effects on the cardiovascular system and potentially disrupt the central nervous system (Refs. 14, 15). (See also section VIII.C discussing the increase in poisoning due to accidental nicotine ingestion.)

(Comment 180) FDA received a large number of comments discussing the addictive nature of nicotine and the impact of nicotine on adolescents. Several comments stated that research indicates that the adolescent brain is more vulnerable to nicotine addiction than the adult brain. The comments noted that researchers have found that, "most likely owing to its ongoing development, the adolescent brain is more vulnerable to the effects of nicotine than the adult brain. Adolescents progress faster to nicotine dependence than adults, find nicotine more rewarding, underestimate the risks of smoking, and are more influenced by smoking behavior in their social milieu." (Refs. 207, 208). One comment noted that animal research showing the adolescent brain is particularly vulnerable to nicotine addiction, and that adolescents are also less susceptible to withdrawal symptoms, creating an all-reward, no-regret system for psychostimulant use (Refs. 209, 210, 211). Another comment noted that the U.S. Surgeon General has found that key symptoms of nicotine dependence—such as withdrawal and tolerance—develop in adolescents following even minimal exposure to nicotine. Additionally, the comment stated that the Surgeon General's 2012 report cites one study following occasional adolescent smokers that found that a large proportion experienced at least one symptom of nicotine dependence upon quitting, even in the first 4 weeks after initiating monthly smoking (at least two cigarettes within a 2-month period) (Ref. 49 at 24, citing Ref. 212).

(Response) FDA agrees that given their developmental stage, and the fact that brain maturation continues into the mid-twenties, adolescents and young adults are more uniquely susceptible to biological, social, and environmental influences to use and become addicted to tobacco products. If individuals do not start using cigarettes by age 26, they are unlikely ever to smoke (Ref. 3). Research shows that 87 percent of established adult smokers began smoking before the age of 18 (Ref. 9). An analysis by the WHO of studies performed among final-year high school students in the United States suggests that fewer than two out of five smokers who believe that they will quit within 5 years actually do quit. In high-income countries, about 7 out of 10 adult smokers say they regret initiating smoking and would like to stop (Ref. 213).

In addition, FDA agrees that there are data suggesting that the adolescent brain is more vulnerable to developing nicotine dependence than the adult brain and that there is evidence to suggest that these brain changes are permanent (Refs. 49, 214). The Surgeon General reported that "most people begin to smoke in adolescence and develop characteristic patterns of nicotine dependence before adulthood" (Ref. 3). These youth develop physical dependence and experience withdrawal symptoms when they try to quit smoking (id.). As a result, addiction to nicotine is often lifelong (Ref. 4). Additionally, youth and young adults generally "underestimate the tenacity of nicotine addiction and overestimate their ability to stop smoking when they choose" (Ref. 5). For example, one survey revealed that "nearly 60 percent of adolescents believed that they could smoke for a few years and then quit" (Ref. 7). Research conducted in animal models have indicated that exposure to substances such as nicotine can disrupt adolescent brain development and may have long-term consequences on executive cognitive function and on the risk of developing a substance abuse disorder and various mental health problems as an adult (Ref. 8). This exposure to nicotine can also have long-term results on decreasing attention performance and increasing impulsivity which could in turn promote the maintenance of nicotine use behavior (id.).

B. Dissolvables

FDA noted in the NPRM that it was proposing to deem certain dissolvable products (*i.e.*, those dissolvable products that do not currently meet the definition of "smokeless tobacco" in section 900(18) of the FD&C Act because they do not contain cut, ground, powdered, or leaf tobacco and instead contain nicotine extracted from tobacco). We explained that little evidence is available to ascertain the pharmacological properties and harmful effects of dissolvable tobacco products or compare them with FDA-approved nicotine replacement products or other tobacco products. We also noted that certain dissolvable smokeless tobacco products, given their candy-like appearance, have the potential for unintended poisonings. FDA deems these dissolvable products with this final rule.

(Comment 181) Comments stated that FDA should not rely on a study investigating flavored tobacco products in young adults as evidence that dissolvables are more attractive to children. They indicated that this study is inapplicable because it only looked at behaviors of people 18 years or older.

(Response) The cited study (Ref. 54) assessed the prevalence of flavored tobacco products (including dissolvables) in individuals 18 and older, which encompasses both young adults and adults. The study stated that the products' packaging looks like candy packaging and the products often are sold next to candy. FDA believes that these factors cause confusion regarding the safety of these novel tobacco products for adult consumers as well as children (Ref. 215). In addition, this study cited an additional study that concluded that sugar preference is greater in youth and young adults (Ref. 53). Accordingly, FDA believes it was appropriate to cite to this study as evidence supporting FDA's concerns with certain dissolvable products.

(Comment 182) Some comments expressed concerns regarding possible confusion between dissolvable tobacco products and candy and the possibility of inadvertent poisonings.

(Response) FDA agrees that the candy-like appearance of some dissolvable products may result in accidental poisonings. As FDA discussed in the NPRM, data from 2010 indicates that 13,705 tobacco product ingestion cases were reported and more than 70 percent of those cases involved infants under a year old (Ref. 215). Although it is unclear exactly how many of these cases involved dissolvables, smokeless tobacco products (in all forms, including dissolvables) were the second most common tobacco product ingested by children, after cigarettes (id.).

(Comment 183) Some comments mentioned that dissolvable tobacco products may be easily confused with NRTs and, therefore, should be regulated.

(Response) The Agency finds that FDA regulation of all dissolvable products under chapter IX of the FD&C Act will help to alleviate potential confusion about the safety and use of these products. Products that contain nicotine derived from tobacco, are intended for human consumption, and are not marketed for therapeutic purposes, are subject to FDA's tobacco product authorities under chapter IX of the FD&C Act.

(Comment 184) Comments provided unpublished data (Ref. 216) indicating that dissolvable tobacco products deliver nicotine levels sufficient to promote and sustain addiction. They also indicated that dissolvable tobacco products have a higher average pH than other tobacco products, increasing the amount of absorbable nicotine.

(Response) FDA acknowledges that information about harmful or potentially harmful constituents in such products is sparse, but studies indicate that the level of nicotine in dissolvable products may differ from cigarettes and may lead to nicotine addiction (Ref. 217). These studies support the public health need to regulate all dissolvable tobacco products.

(Comment 185) Comments stated that dissolvable tobacco products are safer than other tobacco products and have lower levels of nitrosamines than snus or snuff and just slightly higher levels than some NRTs (Ref. 218). They also provided information that evaluated plasma nicotine levels, heart rates, and reduction in cigarette cravings, and found that the levels in certain dissolvables were similar to the levels in NRTs (Ref. 219).

(Response) While a continuum of nicotine-delivering products exists, deeming all tobacco products will enable the Agency to collect information about the ingredients and the health and behavioral effects of these products. These products are "tobacco products" with the potential to addict users and harm children, particularly given their candy-like appearance, and are subject to FDA's tobacco control authorities upon the effective date of this final rule. FDA also notes that NRTs are regulated products and subject to premarket review by FDA.

C. Gels

As proposed, FDA is deeming nicotine gels with this final rule.

(Comment 186) Some comments agreed that nicotine gels should be subject to FDA's chapter IX authorities under the FD&C Act. In support of their argument, they provided studies showing that children and young adults are more susceptible than adults to nicotine poisoning through the skin (Ref. 220).

(Response) With this final rule, FDA is finalizing its proposal to deem all "tobacco products" including nicotine gels, which are absorbed through the skin. In addition to meeting the definition of "tobacco product," nicotine gels can be addictive and lead to use of other tobacco products that have well-documented risks of tobacco-related death and disease. Regulating these products also will help, among other things, to address consumers' unsubstantiated beliefs that non-cigarette tobacco products are safe alternatives to cigarettes.

D. Pipe Tobacco

FDA proposed to cover pipe tobacco with this deeming rule. FDA indicated that pipe tobacco smokers have a risk of tobacco-related disease similar to the risk of those who inhale cigar smoke or smoke cigarettes (Ref. 221). The Surgeon General also found that pipe and cigar smokers experience oral and laryngeal cancer risks similar to that of cigarette smokers (Ref. 222). FDA is deeming pipe tobacco with this final rule.

(Comment 187) A few comments provided suggestions as to how FDA should define pipe tobacco in this final rule to differentiate it from roll-your-own tobacco. For example, comments suggested FDA define pipe tobacco to include the moisture measured at the time of packing, the amount of reducing sugars, and the fact that it does not use reconstituted sheet tobacco or expanded leaf tobacco as part of the blend. Others suggested FDA define the term based on the "consumer's reasonable perception of the product" or include language stating that it is "suitable for use and likely to be offered to, or purchased by, consumers as tobacco to be smoked in a pipe." Comments also requested that FDA enforce against the misuse of pipe tobacco as roll-your-own tobacco, regardless of whether it defines pipe tobacco, because mislabeled pipe tobacco already meets the definition of cigarette tobacco or roll-your-own tobacco.

(Response) FDA disagrees. The Agency finds that it is not necessary to define pipe tobacco in this rule. FDA also notes that it has issued Warning Letters for products bearing the package description of "pipe tobacco," but that are sold or distributed for use as cigarettes for the purposes of chapter IX of the FD&C Act due to the fact that, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, it is suitable for use and likely to be offered to consumers as cigarettes, and/or likely to be purchased by consumers for making cigarettes or intended for use in cigarettes. FDA will continue to do so as circumstances warrant.

(Comment 188) Comments stated that when consumers use pipe tobacco for its intended use, it does not have the same public health concerns as other tobacco products. They also stated that pipe tobacco users are only a small percentage of adults and that only 0.2 percent of minors indicate that they are dual users of pipe tobacco and cigarettes (Ref. 9). They stated that based on these differences, some of the automatic deeming provisions should not apply to pipe tobacco. For example, they claimed premarket review requirements should not apply to pipe tobacco, because manufacturers make changes to maintain consistent taste for older populations and not to create "new" products.

Other comments disagreed, citing evidence of the dangers of pipe tobacco, as discussed in the NPRM (79 FR 23142 at 23156 and 23168). They also expressed concerns that extended use of pipe tobacco releases significant amounts of secondhand smoke into the environment.

(Response) FDA disagrees that pipe smoking is not a public health issue. As we stated in the NPRM, studies of pipe tobacco smokers have found that their risk of tobacco-related disease is similar to the risk in those who inhale cigar smoke or smoke cigarettes (Ref. 221). The Surgeon General also previously found that pipe and cigar smokers experience oral and laryngeal cancer risks similar to that of a cigarette smoker (Ref. 222). While the Surgeon General's report does indicate that pipe tobacco smokers may have a lower risk of developing cardiovascular disease than cigarette smokers, pipe tobacco users still are at risk for these diseases, and those who use both cigarettes and pipe tobacco may have even higher levels of risk due to their usage patterns (Ref. 9 at 428). Moreover, researchers have found that when compared with individuals who have never used tobacco, pipe smokers have an increased risk of death from cancers of the lung, oropharynx, esophagus, colorectum, pancreas, and larynx, and from coronary heart disease, cerebrovascular disease, and COPD (Refs. 32, 221).

(Comment 189) A few comments expressed concern that retailers who blend pipe tobacco would be subject to all FD&C Act requirements for manufacturers, preparers, compounders, or processors of tobacco products, such as premarket review, and registration and listing. These comments requested that retailers blending up to either 3,000 pounds or 5,000 pounds of pipe tobacco per year be exempt from the requirements of the law that apply to manufacturers.

(Response) All entities that meet the definition of "tobacco product manufacturer" in section 900(20) of the FD&C Act, including retail establishments that blend pipe tobacco, are subject to and must comply with all applicable statutory and regulatory requirements for tobacco product manufacturers.

E. Waterpipe Tobacco

The NPRM included waterpipe tobacco as an example of a tobacco product that would be covered under this deeming rule. We noted concerns regarding the safety of waterpipe tobacco given the nicotine and carcinogens in waterpipe tobacco smoke, and the availability of waterpipe tobacco in a variety of flavors that could be appealing to youth and young adults. FDA's final rule includes waterpipe tobacco in the scope of products subject to FDA's tobacco control authorities.

(Comment 190) One comment requested that FDA clarify whether the term "hookah" refers to the waterpipe or the tobacco used in the waterpipe.

(Response) In the NPRM, FDA generally used the term "hookah" to mean waterpipe smoking and "hookah tobacco" as the tobacco used in the waterpipe. Waterpipe smoking may also be referred to by other names such as shisha or narghile. To alleviate any confusion in this final rule, FDA has referred to "waterpipe smoking" and "waterpipe tobacco" to cover all types of tobacco smoking using a waterpipe.

(Comment 191) At least one comment expressed concern about the public health risk of herbal waterpipe tobacco, which they assert has the same levels of toxicant exposure but without nicotine.

(Response) FDA's tobacco product authorities under chapter IX of the FD&C Act do not extend to substances that are not made or derived from tobacco (like herbal waterpipe tobacco), because they do not meet the definition of "tobacco product" under section 201(rr) of the FD&C Act.

1. Dual and Polytobacco Use

(Comment 192) Many comments expressed concern about the growth in dual and polytobacco use among youth and young adults. For example, the North Carolina Public Health Association submitted a preliminary analysis of the 2013 NCYTS, which indicated that 19.1 percent of high school students reported using two or more tobacco products and that 88.4 percent of high school students who currently are using waterpipe tobacco reported using at least one other tobacco product. Some comments noted that dual use of waterpipe tobacco and cigarettes is more prevalent than exclusive waterpipe tobacco use and that waterpipe tobacco users typically smoke cigarettes with greater intensity than nonwaterpipe tobacco users (Ref. 222). In fact, dual use of waterpipe tobacco and cigarette use is one of the most common tobacco use profiles found in young adults age 18 to 24 years (*e.g.*, Ref. 223).

(Response) FDA remains concerned about the potential for dual and polytobacco use, particularly among youth and young adults. As the North Carolina research shows, a noncigarette tobacco product (like waterpipe tobacco) can be the first product used by new tobacco users and there is concern such users could continue using the initial product or transition to cigarettes or other tobacco products. There is also the concern that existing users could become dual users. Accordingly, it is critical to deem these noncigarette tobacco products and place restrictions upon them that are appropriate for the protection of the public health, including age and identification restrictions to help prevent youth use of these products.

2. Popularity

(Comment 193) Many comments expressed concern about the growing use of waterpipe tobacco, particularly among young adults. For example, they noted that the percentage of young adults aged 18 to 24 who use waterpipe tobacco (7.8 percent) is significantly higher than adult use (1.5 percent) (Ref. 224). A few comments suggested that FDA overestimated this trend.

(Response) FDA agrees with the many comments that supported regulation of waterpipe tobacco and noted the increase in use among young adults. Waterpipe tobacco use continues to increase in popularity, particularly among college students, with as many as 40 percent reporting ever using waterpipe tobacco and 20 percent reporting use (*i.e.*, use within the past 30 days) on some college campuses (Refs. 25, 26).

3. Harms

(Comment 194) Many comments supplemented the data in the NPRM regarding the dangers of smoking waterpipe tobacco. For example, they referred to several studies showing significant nicotine, carbon monoxide, and other carcinogen intake during waterpipe use (*e.g.*, Refs. 225, 226, 227, 228). Further, in studies involving the use of waterpipes in a hospital research ward, researchers found greater carbon monoxide exposure and a different pattern of carcinogen exposure for waterpipe tobacco smokers (when compared to cigarette smokers), and concluded that exposure to tobacco smoke toxicants during waterpipe use is similar qualitatively (though not quantitatively) to cigarette smoke (Refs. 229, 230). Comments concluded that waterpipe users have a significant risk of smoking-related diseases, but the magnitude of the risk depends upon the extent of the use.

(Response) FDA agrees with this assessment and that it supports finalizing its proposal to include waterpipe tobacco in the scope of this rule.

(Comment 195) Many comments included data regarding the increased cancer risks associated with waterpipe smoking. For example, researchers identified significant associations between waterpipe tobacco use and esophageal squamous cell carcinoma and a 6-fold increase in risk of lung cancer from waterpipe tobacco use (Refs. 231, 232). In addition, the existence of tobacco-related toxicants in waterpipe tobacco smoke may place users at risk for many of the same diseases as cigarette smokers, including a risk of lung cancer and respiratory illness (*e.g.,* Refs. 233, 234, 235, 236). While some comments maintained that many of these users will use waterpipe tobacco only once in their lifetime, these products are growing in popularity with youth and young adults and cause tobacco-related death and disease.

Other comments opposed FDA's proposal to regulate waterpipe tobacco, claiming that the dangers of waterpipe tobacco use are unsupported, that FDA has not adequately reviewed scientific studies, and that FDA ignored evidence. They also believed that use of disposable mouth piece tips would alleviate the risks of spreading communicable diseases through waterpipe use. In addition, they indicated that FDA's comparison of a waterpipe smoking session to smoking a single cigarette is inherently flawed due to the different patterns of use of these tobacco products.

(Response) Although it is possible that use of disposable mouth piece tips could help alleviate the risks of spreading communicable diseases through waterpipe use, the products nevertheless present a significant risk of smoking-related diseases. Accordingly, FDA is finalizing its proposal to include waterpipe tobacco in the scope of this rule. Further, although the products have different use topographies, FDA continues to believe that a comparison between the toxicants emitted during a waterpipe session and cigarette smoking is valid and indicative of the dangers associated with waterpipe use. In fact, the WHO study group on tobacco regulation has found that a waterpipe session can be the equivalent of smoking more than 100 cigarettes (Ref. 237). Moreover, regardless of the number of waterpipe tobacco users who use waterpipe tobacco for more than 1 day, the product presents significant health risks and is appropriately included in the scope of this rule.

4. Addiction

(Comment 196) Some comments claimed that waterpipe tobacco smokers do not get addicted and, therefore, there is no need for FDA to regulate waterpipe tobacco. Others disagreed and claimed that waterpipe tobacco is addictive. These comments provided extensive data about the significant health effects (including nicotine and toxicant exposure) and the highly addictive nature of waterpipe use (*e.g.,* dual use) (*e.g.,* Ref. 233).

(Response) Waterpipe tobacco contains nicotine, which is the primary addictive chemical in tobacco products. Researchers have observed nicotine dependence characteristics in some users, including suppressed cravings to smoke and anxiousness (Refs. 238, 239, 240), with one study showing that waterpipe tobacco use suppressed withdrawal symptoms just as cigarette smoking suppresses withdrawal symptoms (Ref. 240).

5. Misunderstanding

(Comment 197) Consumers stated that waterpipe tobacco should be regulated given its appeal to youth and adolescents' belief that it is not as harmful as traditional cigarettes. They agreed that a failure to regulate the proposed deemed products could reinforce consumers' existing confusion and misinformation about these products. However, other comments stated that FDA's concerns over youth's misperception of the safety of certain tobacco products should not be a factor that FDA should consider in deciding whether to regulate them. They stated that regulation cannot remedy the fact that certain youth affirmatively disregard available safety information. Comments noted that waterpipe tobacco users perceive this product to be much less harmful that cigarette smoking (Ref. 241), because they mistakenly think that the water filters out toxicants from the smoke and the fact that waterpipe tobacco use is frequently exempted from clean indoor air laws.

(Response) While we continue to believe that alleviating misperceptions is important, we note that the potential to alleviate youth's misperception regarding the toxicity of unregulated tobacco products was only one of many public health benefits associated with deeming tobacco products, as discussed in the NPRM (79 FR 23142 at 23148 and 23149). Waterpipe smoking carries health risks similar to smoking cigarettes, and waterpipe smoke contains many of the same carcinogens and heavy metals as cigarette smoke (79 FR 23142 at 23156 and 23157). In addition, given that waterpipe tobacco smoking sessions last significantly longer than smoking a cigarette, smoking waterpipe tobacco could potentially be even more dangerous than smoking a cigarette (79 FR 23142 at 23156). Consequently, based on the various impacts on public health, FDA believes regulation of waterpipe tobacco is important.

F. Additional Novel and Future Tobacco Products

In the NPRM, FDA proposed to deem additional novel and future tobacco products if the products meet the definition of "tobacco product" in section 201(rr) of the FD&C Act. FDA is finalizing this proposal here.

(Comment 198) Several comments supported deeming all future tobacco products. One comment requested that the future regulated products should include products that extend beyond buccal or dermal absorption.

(Response) Future products that meet the definition of "tobacco product" under section 201(rr) of the FD&C Act, including the requirement that they be "intended for human consumption," are deemed subject to FDA's chapter IX authorities as a result of this rule. A product may be intended for human consumption in a variety of ways, such as through the lungs or by buccal or dermal absorption. However, future accessories of newly deemed products are not deemed subject to chapter IX as a result of this rule.

(Comment 199) At least one comment cautioned FDA that regulations for future products should be based on the continuum of risk to ensure that there is continued innovation to reduce harm.

(Response) FDA recognizes the existence of a continuum of nicotine-delivering products and will continue to consider this continuum in regulating future tobacco products.

(Comment 202) A few comments stated that FDA should not regulate products with de minimis amounts of nicotine derived from tobacco that may be used in cosmetics, food, animal feed, or other products, and for purposes not related to traditional tobacco use (such as protein). Additionally, they stated that these types of products should not have to bear the warning, "This product is derived from tobacco."

(Response) With this final rule, FDA deems all products meeting the definition of tobacco product, except for accessories of newly deemed products, to be subject to FDA's authorities under chapter IX of the FD&C Act.

Determinations about whether particular products meet this definition would be made on a case-by-case basis. However, animal feed is a veterinary product and not for human consumption and, therefore, would not be a tobacco product. Products that contain nicotine derived from tobacco meet the definition of a tobacco product under the FD&C Act and are required to bear a health warning on packages and in advertisements stating: "WARNING: This product contains nicotine. Nicotine is an addictive chemical." For products that are made or derived from tobacco (but do not contain nicotine), manufacturers may submit a certification to FDA and, instead, bear the statement "This product is made from tobacco." See section XVI.H for additional information regarding this certification.

(Comment 203) One comment stated that alternative nicotine products, such as nicotine toothpicks, have a net positive impact on the public health because they pose fewer health and safety risks than conventional cigarettes and could help addicted smokers transition to less toxic tobacco products. The comment argued that the regulatory burden for such products should be proportionately reduced.

(Response) While FDA recognizes the existence of a continuum of nicotine-delivering products, all tobacco products are addictive and potentially dangerous and, therefore, should be subject to FDA regulation. Therefore, FDA is deeming all tobacco products (except accessories of newly deemed tobacco products) subject to the requirements of chapter IX of the FD&C Act and requiring certain additional provisions (*i.e.*, minimum age and identification, vending machine, and health warnings) for covered tobacco products. FDA will continue to take this continuum of nicotine-delivering products into consideration as it contemplates future regulations of the newly deemed products.

XI. Additional Automatic Provisions Applicable to Newly Deemed Products

In addition to the requirement that non-grandfathered tobacco products obtain authorization through one of the three marketing pathways, several provisions in the Tobacco Control Act and its implementing regulations will automatically apply to the newly deemed products as of the effective date of this final rule (79 FR 23142 at 23148 and 23149). These provisions include:

(1) Adulteration and misbranding provisions (sections 902 and 903 of the FD&C Act);

(2) Ingredient listing and HPHC reporting requirements (sections 904 and 915 of the FD&C Act);

(3) Registration and product listing requirements (section 905 of the FD&C Act);

(4) Prohibition against the use of "light," "low," and "mild" descriptors and products with other unauthorized modified risk claims (section 911 of the FD&C Act); and

(5) Prohibition of free samples of the proposed deemed products (21 CFR 1140.16(d)).

Comments regarding these provisions, and FDA's responses to comments, are as follows.

(Comment 204) In the proposed deeming rule, FDA noted that it was taking this action to address the public health concerns associated with the use of tobacco products. Some comments stated that health policies based on tobacco use prevention and cessation are not sufficient to protect the public health.

(Response) FDA is deeming products that meet the definition of "tobacco product," except accessories of newly deemed tobacco products, to address the public health concerns with these products. In the NPRM, FDA included discussion of public health benefits to better inform the public about the likely results of deeming these tobacco products. FDA intends to supplement this final rule with regulations as appropriate to protect the public health.

A. Sections 902 and 903—Adulteration and Misbranding

In the proposed deeming rule, we explained that the adulteration and misbranding provisions of sections 902 and 903 of the FD&C Act would subject all tobacco products to certain basic requirements. For example, their labeling and advertising cannot be false or misleading, which will help reduce consumer confusion and misperception. The Agency can take enforcement action against any tobacco product that did not meet these basic requirements.

(Comment 205) A large number of comments discussed the applicability of sections 902 and 903 of the FD&C Act to the newly deemed tobacco products. Most comments expressed general support for applying adulteration and misbranding provisions to the newly deemed tobacco products. Others supported the application of the provisions based on concerns that some e-cigarette manufacturers may not be producing their products in sterile conditions. Several comments cautioned that the differences between the newly deemed tobacco products might result in unwarranted restrictions if the provisions are applied mechanically across all product categories. At least one comment stated that the adulteration and misbranding provisions should not apply to e-cigarettes because there is no evidence that adulteration and misbranding currently occurs with those products or causes any harm.

(Response) The adulteration and misbranding provisions of sections 902 and 903 of the FD&C Act will automatically subject all tobacco products to certain basic requirements. For example, their labeling and advertising cannot be false or misleading, which will help reduce consumer confusion and misperception. FDA will be able to take enforcement action against any tobacco product that does not meet these basic requirements. For example, if a product is produced in insanitary conditions or is contaminated, or if its labeling contains a misleading claim, it will be subject to enforcement action, including seizure and injunction.

B. Sections 904 and 915—Ingredient Listing and Reporting of HPHCs

As stated in the NPRM, the newly deemed products will be required to comply with the ingredient listing and HPHC reporting requirements of sections 904 and 915 of the FD&C Act. FDA intends to issue a guidance regarding HPHC reporting, and later a testing and reporting regulation as required by section 915, with enough time for manufacturers to report given the 3-year compliance period for HPHC reporting. As noted elsewhere in this document, FDA does not intend to enforce the reporting requirements for newly deemed products before the close of the 3-year compliance period, even if the guidance is issued well in advance of that time.

(Comment 206) A couple of comments urged FDA not to require newly deemed products to comply with the ingredient and HPHC listing requirements. One comment argued that such reports are useless for educating consumers, who will invariably use them in an attempt to determine the relative risk of each product. Another comment claimed that the HPHC and ingredient listing requirements should be abandoned because they are not helpful and the cost of producing these reports would destroy industry.

(Response) FDA disagrees with these comments. Ingredient and HPHC reporting assist FDA in better understanding the contents of regulated products. This information will assist FDA in assessing potential health risks and determining if future regulations to address these health risks would be appropriate. The FD&C Act directs FDA to make certain HPHC information publicly available, but it must do so in a way that is understandable and not misleading to lay persons.

(Comment 207) Several comments discussed ingredient and HPHC listing requirements in the context of small businesses and particular products. A few comments urged FDA to exempt small businesses that manufacture e-cigarettes from the HPHC reporting requirement because the testing would impose a large financial burden on them and would likely drive them out of business. One comment countered these arguments, urging FDA to require manufacturers of all products to comply with the ingredient and HPHC listing requirements and not provide an exemption for small businesses. The comment argued that the size of a business does not change a product's potential health impact and that the health benefits of regulation far exceed the costs.

Other comments focused on ingredient and HPHC listing requirements for specific product categories. At least one comment expressed concern that HPHC testing would disproportionately affect the premium cigar industry, which has a high number of low-volume products, and requested that the requirements not apply to small batch or special release products. One comment claimed that many of the new tobacco products on the market, such as e-cigarettes, are virtually identical with the exception of flavoring and nicotine levels and recommended that FDA allow for these products to be grouped together for the purposes of HPHC testing.

(Response) With respect to HPHC testing of similar products, FDA recognizes that some manufacturers of newly deemed products sell products in various flavors or with varying levels of nicotine. Manufacturers of these products will be required to test each variation for HPHCs, even where the products are otherwise the same. At this time, there is little known about the constituents of some newly deemed products. HPHC testing will allow FDA to track the level of HPHCs across different categories of flavors and by nicotine level. FDA's compliance policies for the HPHC requirements are described elsewhere in this document.

(Comment 208) Several comments stated that FDA should establish HPHC lists and testing methodology before requiring HPHC testing. One comment requested that FDA establish an HPHC list and testing methodology for e-cigarettes in the same manner that it did for currently regulated tobacco products, including holding public workshops, requesting and considering Tobacco Products Scientific Advisory Committee recommendations, publishing draft and final lists in the **Federal Register** for public comment, and providing a reasonable compliance period for e-cigarette manufacturers. A few comments expressed the opinion that FDA should establish separate lists of HPHCs for each category of newly deemed tobacco products and not require HPHC reporting until the lists and corresponding testing methodologies are created and validated. Other comments stated that because not all deemed products are likely to have the same HPHCs as currently regulated products, testing for all of the constituents would be wasteful.

(Response) As discussed elsewhere in this document, the compliance period for HPHC reporting and testing is the effective date of this rule plus 3 years. FDA intends to issue a guidance regarding HPHC reporting, and later a testing and reporting regulation as required by section 915 of the FD&C Act, with enough time for manufacturers to report given this compliance period. As noted elsewhere in this document, FDA does not intend to enforce the reporting requirements for newly deemed products before the close of the 3-year compliance period, even if the guidance is issued well in advance of that time.

(Comment 209) Several comments suggested that manufacturers should be required under section 904 of the FD&C Act to include a statement of the ingredients and/or nicotine concentration on their product labeling as a condition of sale. These comments indicated that consumers could use this information to select e-cigarette liquids with decreasing nicotine content levels as part of a nicotine replacement therapy to quit smoking.

(Response) Sections 915(b) of the FD&C Act and 206 of the Tobacco Control Act give FDA authority to require the disclosure of nicotine and certain other information on labeling and by other means. FDA has not issued regulations for the currently regulated tobacco products and did not propose this in the proposed deeming rule. FDA will consider whether it should do so in the future. To the extent the comment is about ENDS marketed for smoking cessation, such a product would be subject to FDA's drug/device authorities and not subject to FDA's tobacco product authorities.

(Comment 210) Some comments suggested that any HPHC requirement for cigars should require analysis of HPHCs in the tobacco (rather than the smoke) in a manner similar to that for hand-rolling tobacco. They stated that HPHC smoke analysis is neither available nor readily producible for most cigars. They also stated that smoking regimens recommended for collecting HPHC data for tobacco smoke were developed for cigarettes and suggested that cigars are inherently more variable than cigarettes. Finally, they stated that the cigar smoke test method recommended by the Centre de Coopération pour les Recherches Scientifiques Relatives au Tabac in 2005 has produced more variable data than that obtained using the comparable test method for cigarettes, making it difficult to compare consistent test results for cigars.

(Response) FDA disagrees with the comments. In order to determine the HPHC deliveries that each cigar provides, it is important that manufacturers submit HPHC data on smoke yields for cigars. HPHC quantities in cigar tobacco only would not provide a complete understanding of the toxicity of each cigar. As stated by the comments, Centre de Coopération pour les Recherches Scientifiques Relatives au Tabac (CORESTA) published method 64 in 2005 that describes a smoking regimen for cigars. It is not clear that the variability in cigar HPHC yields will be greater than that for cigarette yields. Variability in HPHC smoke yields is dependent on the smoking regimen, analytical method, and batch-to-batch consistency in product composition. Therefore, it is expected that the variability in HPHC smoke yields from some cigarettes will exceed that for cigars. In any case, as with cigarettes, it is important to understand the HPHC deliveries in cigar smoke.

C. Section 905—Registration and Listing

As stated in the NPRM, manufacturers of the newly deemed products will be required to comply with section 905(b) of the FD&C Act, which requires the registration of any establishment engaged in the manufacture, preparation, compounding, or processing of a tobacco product. In addition, they must comply with section 905(i) of the FD&C Act, which requires registrants to submit a list of all tobacco products that are being manufactured, prepared, compounded, or processed for commercial distribution. FDA must issue a regulation before foreign establishments are required to comply with these requirements.

(Comment 211) Several comments stated that FDA should apply the same requirements to both foreign and domestic manufacturers of tobacco products, including manufacturers of the newly deemed products. They expressed concern that FDA has not yet issued a proposed registration and listing rule and has not provided a timeframe for a final rule that would apply these requirements to foreign establishments. They also stated that the absence of registration and listing requirements for foreign establishments creates incentives for manufacturers of the newly deemed products to move their facilities overseas.

(Response) As indicated in the Unified Agenda of Spring 2015 (Ref. 242), FDA plans to issue a proposed registration and listing rule that would extend these requirements to foreign tobacco product establishments. In addition, upon the effective date of this final deeming rule, both foreign and domestic manufacturers will be subject to, among other things, adulteration and misbranding restrictions (sections 902 and 903 of the FD&C Act); requirements for ingredient listing and reporting of HPHCs for all tobacco products (section 904 of the FD&C Act); and premarket authorization requirements (sections 905 and 910 of the FD&C Act).

D. Section 911—Elimination of Low, Light, and Mild, and Other Unauthorized Modified Risk Claims

Section 911 of the FD&C Act is one of the automatic statutory provisions that will apply to the newly deemed products on the effective date of this regulation. The purpose of this section is to prohibit the introduction into interstate commerce of MRTPs, including products the label, labeling, or advertising of which uses "low," "light," or "mild," or other modified risk claims unless FDA issues an order authorizing their marketing. This requirement will help consumers better understand and appreciate the health risks of the newly deemed products. In addition to any applicable premarket review under section 910 of the FD&C Act, if a manufacturer wishes to sell a MRTP, the company must submit an MRTP application under section 911 and receive an FDA order to legally market an MRTP.

(Comment 212) A number of comments discussed the application of the MRTP restrictions to the newly deemed products. Several comments argued, as a general matter, that subjecting the newly deemed products to section 911 would be an unconstitutional restriction of free speech because FDA either has no substantial interest that would be advanced by such restrictions or has not demonstrated that restricting modified risk claims for these products would advance its substantial interest in protecting the public health. A couple of comments argued that the brand names of newly deemed products that contain the descriptor "low," "light," or "mild" should be prohibited only where the descriptors specifically convey a modified risk claim. These comments stated that where "low," "light," or "mild" is used and understood by consumers to describe something other than a modified risk (such as the product's taste), restricting the use of a brand name containing one of these terms would be unconstitutional, arbitrary, and capricious because the government does not advance any substantial interest by doing so. Other comments supported the application of section 911 to all newly deemed tobacco products, with some comments maintaining that certain e-cigarette companies are currently marketing their products using unauthorized modified risk claims.

(Response) FDA disagrees with the suggestion that subjecting the newly deemed products to section 911 would be an unconstitutional restriction of free speech. The Sixth Circuit upheld the modified risk provisions against a First Amendment challenge to the facial validity of the statute in *Discount Tobacco* v. *FDA*, 674 F.3d 509, 531–37 (6th Cir. 2012). We discuss this issue in depth in section II.B.3.b. FDA has and will continue to apply section 911 of the FD&C Act consistent with the First Amendment and will take all relevant facts into account on a case-by-case basis.

FDA agrees with comments that supported the application of section 911 to all newly deemed products. Historically, certain users have initiated and continued using certain tobacco products based on unauthorized modified risk claims and consumers' unsubstantiated beliefs about the relative safety of these products. Section 911 will prevent the use of unsubstantiated modified risk claims, which may mislead consumers and lead them to initiate tobacco product use or to continue using tobacco when they would otherwise quit. This will allow for better-informed consumers and help to prevent the use of misleading marketing targeted to youth populations.

(Comment 213) Many comments stated that e-cigarette companies make direct and indirect health claims in the marketing and promotion of their products (*e.g.,* by posting customer comments and testimonials on their Web sites) and that some e-cigarette advertising implies FDA approval or endorsement (*e.g.,* use of the FDA logo on labels or statements such as "made in an FDA-approved facility") (Ref. 151). As a result, the comments suggested a number of different actions to curb these unsubstantiated or misleading claims, including: (1) Prohibiting direct and implied therapeutic claims that e-cigarettes are effective cessation products unless there is evidence; (2) using existing enforcement authority to prohibit therapeutic, health, and cessation claims unless there is evidence of safety and efficacy; (3) working with the FTC to prohibit such claims as false advertising until such time as there is evidence of safety and efficacy; (4) working with the FTC to introduce or strengthen disclosure rules on the Internet (*e.g.,* product reviews) to promote transparency; and (5) prohibiting explicit or implicit statements that e-cigarettes are approved or endorsed by FDA.

(Response) Under section 911 of the FD&C Act, no person may introduce or deliver for introduction into interstate commerce any MRTP without an order in effect under section 911(g). Also, a tobacco product is misbranded if its label, labeling, or advertising is false or misleading in any particular. Therefore, by deeming ENDS and other tobacco products, FDA is now authorized to take enforcement action against manufacturers who sell and distribute products with unsubstantiated MRTP claims, or false or misleading claims on their label, labeling, or advertising. Additionally, under section 301(tt) of the FD&C Act, anyone making explicit or implicit statements that a product is, among other things, "approved" or "endorsed by FDA" is committing a prohibited act. An ENDS product claiming to be an NRT or otherwise marketed for therapeutic purposes is a drug or device subject to FDA's regulations and laws for those products. Additionally, the Agency will consider these comments in the future, and, if FDA determines that it is appropriate, will issue additional regulations.

E. Section 919—User Fees

In 2014, FDA issued a final rule regarding user fees for cigarettes, snuff, chewing tobacco, and roll-your-own tobacco, including the submission of information needed to calculate and assess those user fees (79 FR 39302, July 10, 2014). In that final rule, FDA stated that if it deems cigars or pipe tobacco, FDA would respond to the NPRM comments regarding user fee provisions for cigars and pipes, and revise the user fee regulations (79 FR 39302 at 39305).

Accordingly, elsewhere in this issue of the **Federal Register**, FDA is issuing a final rule revising the current user fee regulations.

(Comment 214) Some comments supported applying the user fee provisions of the Tobacco Control Act to all tobacco products, explaining that application of user fee provisions to all products is essential to ensure uniformity and fairness across the regulated entities. They also noted that section 919(b)(3) of the FD&C Act states that no manufacturer or importer of tobacco products shall be required to pay a user fee in excess of the percentage share of such manufacturer or importer. Accordingly, they argued that FDA cannot assess user fees based on the continuum of nicotine-delivering products.

(Response) Elsewhere in this issue of the **Federal Register**, FDA is issuing a final rule regarding user fees for cigars and pipe tobacco, including the submission of information needed to calculate their user fee assessments. These comments are addressed in that rule.

F. Tobacco Control Act, Section 102—Prohibition Against Free Samples

In this final rule, FDA is not modifying the existing restriction on distributing free samples of tobacco products (21 CFR 1140.16(d)). As a result, this restriction will prohibit the distribution of free samples of newly deemed tobacco products, as required by section 102 of the Tobacco Control Act. See section II.B.3.a for discussion regarding the constitutionality of this free sample prohibition.

FDA understands concerns from some retailers about the effect that a ban on free samples would have on their ability to promote new products. FDA wishes to clarify that allowing prospective adult buyers to smell or handle one of the newly deemed products is not considered distribution of a "free sample" as long as the free product is not actually consumed, in whole or in part, in the retail facility and the prospective buyer does not leave the facility with a free tobacco product. For example, affording adult consumers the opportunity to handle a cigar will give them the ability to feel the resistance of the cigar's structure and allow them to clearly see the color of the product, which is an indication of the fermentation period for the tobacco. Handling the product also will allow users to capture the aroma of a cigar and the box (if the cigar is sold in a package). However, if the prospective buyer lights and draws or puffs on the cigar to keep it lit, or otherwise uses the free cigar or leaves the retail establishment with a free cigar (partially used or intact whole), this would constitute a "free sample" in violation of the restriction on free samples mandated by section 102 of the Tobacco Control Act. We believe that, in most circumstances, other retail facilities, including ENDS retail establishments, can similarly allow customers to touch, hold, and smell their products without violating the free sample ban. We note that nothing in this policy should be construed to alter or amend the regulation implementing the free sample ban at § 1140.16.

(Comment 215) A large number of comments discussed whether FDA should allow the continued distribution of free samples of the newly deemed tobacco products. Most comments expressed general support for the ban on free samples, citing concerns that such samples serve as a gateway for youth tobacco initiation. Several comments argued that there is no reason to believe that free samples of pipe tobacco and premium cigars encourage youth initiation because the samples are distributed almost exclusively in adult-only retail operations. One comment claimed that because epidemiological data suggest that the majority of premium cigar smokers fall into a category where there is no significant difference in the incidence of disease compared to never-smokers, banning free samples of premium cigars would have no corresponding benefit even if it did reduce youth initiation. This comment also claimed that it would similarly not help prevent youth access because they assert that, as indicated in a recent SAMHSA survey, there is no evidence that youth obtain premium cigars at all, let alone as free samples from retailers.

Several comments, referring specifically to pipe tobacco, premium cigars, and e-cigarettes, stated that, in light of the lack of evidence that youth obtain free samples of their products, banning these samples, which are a vital part of their industries, would only hurt sales and small businesses without a corresponding public health benefit. Comments referring to premium cigars and pipe tobacco stated that free samples of these products are necessary to entice adult consumers to purchase what are frequently unique and sometimes expensive products. Comments on e-cigarettes argued that, because their products are new, free samples are necessary to convince cigarette users to switch to them.

One comment argued that FDA's proposed ban on free samples impermissibly restricts commercial speech that is protected by the First Amendment. The comment stated that while the court in *Discount Tobacco City & Lottery* v. *United States* upheld the Tobacco Control Act's sampling ban on cigarettes, the evidence the court used to uphold that ban does not support the same ban for the newly deemed tobacco products. The comment argued that FDA has presented no evidence that samples of these products lead to youth initiation and, therefore, the Agency would not be advancing a legitimate government interest with this ban. Additionally, the comment suggested that even if the ban did advance a legitimate government interest, FDA could achieve the same results through less restrictive means, such as by allowing samples in qualified adult-only facilities, as FDA does with smokeless tobacco.

(Response) FDA disagrees with the assertions that the proposed ban on free samples would hurt businesses without corresponding public health benefits or that this prohibition impermissibly restricts commercial speech. This prohibition will eliminate a pathway for youth to access tobacco products, which can help reduce youth initiation and therefore short-term and long-term morbidity and mortality resulting from these products. The IOM has stated that free samples of cigarettes "encourage experimentation by minors with a risk free and cost-free way to satisfy their curiosity" (Ref. 30). While the IOM was speaking in the context of cigarettes, FDA believes that the same rationale applies to the newly deemed products. In addition, the U.S. Court of Appeals for the Sixth Circuit held that the free sample ban as applied to cigarettes does not violate the First Amendment. The court recognized that FDA has provided "extensive" evidence that free tobacco samples constitute an "easily accessible source" for youth (*Discount Tobacco City & Lottery, Inc.* v. *United States,* 674 F.3d 509, 541 (6th Cir. 2012) (citing 61 FR 44396 at 44460, August 28, 1996), *cert. denied sub nom. Am. Snuff Co., LLC* v. *United States,* 133 S. Ct. 1966 (2013)). Moreover, the panel unanimously found that the ban "embodie[d] a narrow fit between the harm articulated and the restrictions employed" (id.). See section II.B.3.a for more detailed discussion of the constitutionality of the free sample prohibition.

FDA understands concerns from cigar retailers about the effect that a ban on free samples would have on their ability to promote new products. FDA wishes to clarify that allowing prospective adult buyers to smell or handle a cigar is not considered the distribution of a "free sample" as long as the product is not actually consumed, in whole or in part, in the retail facility and the prospective buyer does not leave the facility with a free tobacco product. Affording adult consumers the opportunity to handle the product will give them the ability to feel the resistance of the cigar's structure, and allow them to clearly see the color of the product, which is an indication of the fermentation period for the tobacco. It also will allow users to capture the aroma of the cigar and the box (if the cigar is sold in a package). However, if the prospective buyer lights and draws or puffs on the free cigar or otherwise uses the free cigar or leaves the retail establishment with a free cigar (partially used or intact whole), this would constitute a "free sample" in violation of the ban on free samples mandated by section 102 of the Tobacco Control Act. We believe that, in most circumstances, other retail facilities, including ENDS retail establishments, can similarly allow customers to touch, hold, and smell their products without violating the free sample ban.

XII. Requests for Additional Regulations Applicable to Newly Deemed Products

In the NPRM, FDA noted that certain provisions would automatically apply to the newly deemed products and that the Agency was proposing additional restrictions that also would apply to covered tobacco products. FDA also noted that after the final rule becomes effective, the Agency would have the authority to issue additional regulations applicable to the newly deemed products, including product standards under section 907 of the FD&C Act. Many stakeholders submitted comments and data regarding the need for additional requirements and restrictions for the newly deemed products. Some of these requests would require a separate NPRM, and they will help inform FDA as it considers additional regulations for newly deemed products.

A. Ban on Flavored Tobacco Products

FDA received numerous comments regarding flavored tobacco products, including comments expressing concerns regarding the impact of flavors on youth and young adults and preliminary data regarding some individuals' use of flavored ENDS products to transition away from combusted tobacco use. FDA's summary of comments and data regarding flavored tobacco products is included in section V.B of this document. FDA's responses to comments regarding a possible ban on flavored tobacco products are included below.

(Comment 216) Many comments suggested that FDA include a ban on flavored tobacco products with this final rule. Other comments suggested that FDA continue to allow the sale of fruit or candy-flavored e-cigarettes, because they aid cigarette smokers in decreasing cigarette use and in smoking cessation. These comments generally relied on a research article that found that most e-cigarette users switched between flavors on a daily basis or within the day, with former smokers switching more frequently than current smokers, and that respondents indicated that flavor variety was "very important" in reducing or quitting smoking (Ref. 62). This survey also noted that almost half of respondents indicated that a reduction in available flavors would "increase craving[s] for tobacco cigarettes and would make reducing or completely substituting smoking less likely" (id.). Therefore, they believed that FDA should not sacrifice adults' use of flavored tobacco products in an attempt to prevent children from using flavored tobacco products. These comments also noted that flavors are used in other legally marketed products including nicotine replacement therapies (NRTs), which are FDA-approved products.

(Response) FDA is not banning flavored tobacco products with this final deeming rule. To address concerns with the growing flavored cigar market and its impact on youth and young adult initiation with tobacco products, FDA is announcing here that it intends to issue in the future a proposed product standard that would prohibit characterizing flavors in all cigars, including cigarillos and little cigars.

As discussed in section VIII.F of this document, we recognize that there is evidence that some individual former smokers may now report using ENDS (Ref. 24). However, the study referred to in the comments (Ref. 62) examined self-selected research subjects who were recruited through an e-cigarette Web site. All respondents were either former smokers (91.2 percent) or current smokers (8.8 percent); both groups had smoked on average 22 years before beginning to use ENDS. The article did not consider whether either the self-selection or the demographic profile of the respondents might affect the applicability of its results to any larger population. Moreover, the study did not address the question of whether study participants would have increased cigarette use if there were no available flavored ENDS or if the variety of flavored ENDS were limited. If additional evidence emerges that flavored ENDS make it more likely that smokers switch completely to ENDS, such evidence submitted as part of a PMTA would help support that application, as part of the analysis of whether the marketing of the product is appropriate for the protection of public health.

Further, new data shows continued growth in youth and young adult usage of flavored tobacco products. FDA has balanced those concerns with preliminary data showing that some adults may potentially use flavored ENDS to transition from combusted tobacco use when developing the compliance policy for premarket review.

(Comment 217) Many comments responded to FDA's request for data, research, and information regarding the characteristics or factors it should consider in determining whether a particular tobacco product is a "cigarette" as defined in section 900(3) of the FD&C Act and, consequently, subject to the prohibition against characterizing flavors, despite being labeled as a little cigar or other noncigarette tobacco product. Several comments stated that little cigars are being marketed and used as cigarettes and, therefore, FDA should communicate that such products are subject to the cigarette flavor ban. Other comments provided information regarding the differences between cigarettes and little cigars or other noncigarette tobacco products and indicated that such products should not be subject to the cigarette flavor ban.

(Response) FDA understands and appreciates comments regarding the role that flavored little cigars, or similar products, might play on initiation of tobacco product use and dual use. FDA will continue to determine whether a product is a "cigarette" under the FD&C Act and subject to the statutory flavor ban on a case-by-case basis.

(Comment 218) One comment stated that section 907(d)(3) of the FD&C Act, which prohibits FDA from banning certain enumerated tobacco products, demonstrates that Congress did not intend to grant FDA the power to ban any tobacco product by any means, including by enacting a product standard that would be a tantamount ban of newly deemed products, especially when some of these products present lower risks of death and disease than the specifically enumerated ones. Some comments also referred to the difficulty in defining "characterizing flavor" in the context of instituting a ban on flavored newly deemed tobacco products.

(Response) If FDA decides to issue a product standard, it will do so in accordance with section 907 of the FD&C Act. Because FDA is not banning flavored tobacco products with this final deeming rule, it is not necessary to consider whether and how to define "characterizing flavor."

B. Additional Access Restrictions

(Comment 219) Some comments suggested that FDA require face-to-face sales for all covered tobacco products, as it does for sales of cigarettes and smokeless tobacco, as provided in § 1140.14(a)(3). For example, they suggested that FDA ban self-service displays for newly deemed tobacco products. They expressed concern that treating cigarettes and smokeless tobacco differently from other tobacco products would lead to confusion for retailers and complicate retailer training programs.

(Response) FDA will continue to monitor this issue and, if it determines that it is appropriate for the protection of public health to extend the self-service display prohibition to newly deemed tobacco products, the Agency will issue a new NPRM in accordance with the APA.

(Comment 220) Some comments suggested that we simultaneously issue this final rule with an ANPRM seeking additional information to draft a proposal that would apply the additional restrictions in part 1140 (*e.g.,* ban on self-service displays, the sale and distribution of nontobacco items, and the sponsorship of events) to newly deemed products.

(Response) FDA is taking this comment under advisement. If FDA decides to issue such a proposal, the Agency will comply with the requirements of the APA.

(Comment 221) A few comments requested that FDA regulate all dissolvables and other newly deemed products in the same manner it regulates other tobacco products, including application of all of the marketing and advertising restrictions in part 1140.

(Response) At this time, FDA is subjecting newly deemed products to the automatic requirements and covered tobacco products to the additional provisions (*i.e.,* age and identification requirements, vending machine restrictions, and health warning requirements) discussed in this final rule. However, if FDA later determines that extending such marketing and advertising restrictions to the newly deemed products is appropriate and meets the applicable standard in section 906(d), FDA will comply with the requirements of the APA when implementing such restrictions.

C. Nicotine Exposure Warnings

(Comment 222) Many comments expressed concern about the increase in nicotine poisonings due to accidental ingestion of e-liquids and offered suggestions to address this issue: (1) Set a maximum nicotine content level for e-liquids; (2) require the use of child-resistant containers; (3) require a poison warning on the packaging and point of sale for liquid-based products; and (4) set a limit on the allowable speed of flow of the product from its container (*e.g.,* by requiring a flow-restricting apparatus on the opening of the container or requiring a rigid container to prevent quick dispensing of product by squeezing the container).

(Response) FDA expressed similar concerns about the increase in nicotine poisonings in the NPRM and section VIII.D. Once this final rule becomes effective, FDA has authority to issue additional regulations to address these concerns. In addition, FDA has issued an ANPRM prior to this deeming rule, seeking comments, data, research, or other information that may inform regulatory actions FDA might take with respect to nicotine exposure warnings and the use of child-resistant packaging. Moreover, elsewhere in this issue of the **Federal Register**, FDA has made available draft guidance, which when final will describe FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products, including recommendations for nicotine exposure warnings and child-resistant packaging that would help to support a showing that the marketing of a product is appropriate for the protection of the public health.

XIII. Severability

This rule is being finalized with several changes from the NPRM. Specific comments regarding proposed codified language, and FDA's responses to those comments, are included in section VII.

In accordance with section 5 of the Tobacco Control Act, FDA considers and intends the extension of its authorities over all tobacco products and the various requirements and prohibitions established by this rule to be severable. It is FDA's interpretation and position that the invalidity of any provision of this rule shall not affect the validity of any other part of this rule. In the event any court or other lawful authority were to temporarily or permanently invalidate, restrain, enjoin, or suspend any provision of this final rule, FDA would conclude that the remaining parts continue to be valid. As stated in section 5 of the Tobacco Control Act, if certain applications of this rule to persons or circumstances (discussed in the preamble or otherwise) are held to be invalid, application of such provisions to any other person or circumstance will not be affected and will continue to be enforced to the fullest extent possible. Each provision of the rule is independently supported by data and analysis as described or referenced in this preamble and, if issued separately, would remain a proper exercise of FDA authority.

XIV. Description of the Final Rule—Part 1100

In the NPRM, FDA explained that new part 1100 would describe the scope of FDA's authority over tobacco products, the requirements that would apply to tobacco products, applicable definitions, and the effective date of the rule. We consider and intend the extension of our authorities over tobacco products and the various requirements and prohibitions established by this rule to be severable.

A. Section 1100.1—Scope

FDA selects Option 1 with this final rule, deeming all cigars (rather than a subset), which has been applied throughout the codified text for parts 1100, 1140, and 1143. Therefore, this section now states that in addition to FDA's authority over cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco, FDA deems all other products meeting the definition of "tobacco product" under section 201(rr) of the FD&C Act, except accessories of such other tobacco products, to be subject to chapter IX of the FD&C Act. The definition of "accessory" is now included in § 1100.3 (as discussed in section VI.A).

B. Section 1100.2—Requirements

Because FDA selected Option 1 for the scope of the deeming rule, § 1100.2 states that cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco are subject to chapter IX of the FD&C Act and its implementing regulations. In addition, this section states that FDA has deemed all other tobacco products, except accessories of such other tobacco products, subject to chapter IX of the FD&C Act and its implementing regulations.

C. Section 1100.3—Definitions

FDA requested comment on definitions for cigar, covered cigar, and tobacco product. Because we are selecting Option 1 deeming all cigars (rather than a subset) with this final rule, comments regarding the definition of covered cigar are no longer relevant to this rulemaking. In addition, FDA received many comments regarding components, parts, and accessories, including how they should be defined and the application of requirements to these objects. We have added definitions of "component or part" and "accessory" to this section. The discussion of this language is included in section VI.A.

XV. Description of the Final Rule—Part 1140

Currently, part 1140 generally applies to cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. FDA proposed additional provisions to apply to "covered tobacco products" (namely, the requirement to prohibit the sale and distribution of products to individuals under 18 years of age and the prohibition on vending machine sales except in adult-only facilities). As stated elsewhere in this document, "covered tobacco product" means any tobacco product deemed to be subject to the FD&C Act pursuant to § 1100.2, but excludes any component or part that is not made or derived from tobacco. FDA is finalizing these requirements without substantive change. FDA intends to update the current guidance documents for civil money penalties and frequently asked questions to reflect that violations of health warning requirements may lead to the issuance of civil money penalties. We consider and intend the extension of our authorities over tobacco products and the various requirements and prohibitions established by this rule to be severable.

A. Section 1140.1—Scope

The NPRM offered several amendments to part 1140 in order to apply select existing sale and distribution restrictions, including age, identification, and vending machine provisions, to address youth access to the deemed tobacco products. As currently written, part 1140 generally applies to cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco products. Accordingly, FDA is finalizing this rule to add the phrase "and covered tobacco products" to § 1140.1(a) and (b) to ensure the products are subject to select existing restrictions and access provisions. We also have added language to § 1140.1(a) to clarify the scope of § 1140.16(d).

B. Section 1140.2—Purpose

This final rule adds "and covered tobacco products" to indicate that the purpose of this part is to establish restrictions on the sale, distribution, and access to covered tobacco products in addition to those restrictions in place for cigarettes and smokeless tobacco. Therefore, the final rule states that retailers of the newly deemed covered tobacco products may not sell them to individuals under 18 years of age and requires retailers of covered tobacco products to verify the purchaser's birth date by reviewing the individual's photographic identification. However, as noted in § 1140.14(b)(2)(ii), a retailer is not required to verify the age of any person who is more than 26 years of age. In addition, § 1140.14(b)(3) prohibits the sale of covered tobacco products using an electronic or mechanical device such as a vending machine, unless it is located in a facility where the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time. FDA does not intend for section 1140.14(b)(3) to prohibit the sale of tobacco products via the Internet, but the sale of covered tobacco products via any medium, including the Internet, must only be to persons 18 years of age or older. Therefore, any sale of covered tobacco products over the Internet must comply with the minimum age and identification requirements in this rule.

C. Section 1140.3—Definitions

In the NPRM, we sought comments on definitions of the following terms: Cigar, cigarette, cigarette tobacco, covered tobacco product, distributor, importer, nicotine, package, point of sale, retailer, smokeless tobacco, and tobacco product. FDA received many comments regarding whether e-liquids and components, parts, and accessories are tobacco products. FDA also received many comments regarding the need to define components, parts, and accessories, which resulted in the addition of definitions of "component or part" and "accessory" in § 1140.3. The discussion of this language in included in section VI.A. Further, we revised the definition of "package" to refer to "package or packaging." We also added a definition of "roll-your-own" to provide further clarity to the definition of "cigarette."

D. Section 1140.10—General Responsibilities of Manufacturers, Distributors, and Retailers

With the selection of Option 1, § 1140.10 now provides that manufacturers, distributors, importers, and retailers are responsible for ensuring that the covered tobacco products (in addition to cigarettes and smokeless tobacco) they manufacture, label, advertise, package, distribute, import, sell, or otherwise hold for sale comply with all applicable requirements in part 1140. The revisions to §§ 1140.10 and 1140.14 clarify that the minimum age and identification requirements and vending machine restrictions apply to the newly deemed covered tobacco products.

Previously, § 1140.10 stated that each manufacturer, distributor, importer, and retailer is responsible for ensuring that its products comply with all applicable requirements under part 1140. FDA proposed to add "and covered tobacco products" to the existing language of this section to clarify that the provision also applies to "covered tobacco products" as defined in § 1140.3. In addition, FDA proposed that § 1140.10 cover importers, because the Tobacco Control Act defines "tobacco product manufacturer" to include importers (section 900(20) of the FD&C Act), signaling Congress' intent for tobacco product importers to be subject to requirements like those in § 1140.10. FDA is finalizing this section as drafted in the NPRM.

E. Section 1140.14—Additional Responsibilities of Retailers

FDA proposed to divide this section into responsibilities for retailers of cigarettes and smokeless tobacco products and responsibilities for retailers of covered tobacco products. FDA is finalizing this section as drafted in the NPRM. Therefore, upon the effective date of this final rule, § 1140.14(a)(1) through (a)(5) will provide the retailer's responsibilities for the sale of cigarettes and smokeless tobacco. Section 1140.14(b)(1) through (b)(3) will provide the retailer's responsibilities for the sale of newly deemed products.

F. Comments and Responses Regarding Minimum Age and Identification Requirements

In the NPRM, FDA sought comment regarding whether to prohibit the sale of newly deemed products to individuals under 18 years of age and to require photographic identification for individuals aged 26 and under (which are the same requirements that currently apply to cigarettes and smokeless tobacco). FDA discussed the benefits of a uniform minimum age and identification requirement, including: (1) Decreasing youth access to tobacco products in another jurisdiction with less stringent requirements; (2) addressing youth misperceptions that tobacco products without minimum age or identification requirements are safer; and (3) increasing the ease with which retailers can comply with minimum age and identification requirements for covered tobacco products (79 FR 23142 at 23160 23162). In addition, we expressed our intention to use an aggressive nationwide enforcement program to increase compliance and deter youth consumption of tobacco products (79 FR 23142 at 23160).

Nearly all comments supported a minimum age and identification requirement for the newly deemed tobacco products. FDA is finalizing these requirements without change. FDA also intends to update the current guidance documents for civil money penalties and frequently asked questions to reflect that violation of these provisions may lead to the imposition of civil money penalties. A summary of comments regarding these provisions, and FDA's responses, is included in the following paragraphs.

(Comment 223) Many comments supported FDA's proposal due to the fact that many of the newly deemed products are easily available. For example, they noted that tobacco industry documents refer to the increased frequency with which self-service tobacco products are stolen, and some of the proposed deemed products (*e.g.*, cigars) are frequently sold in self-service displays (Ref. 243). They expressed concern that self-service displays increase the likelihood that minors will have access to tobacco products.

(Response) FDA agrees that the newly deemed tobacco products are readily available to consumers. FDA finds that the age and identification restrictions that are included in this final rule (§ 1140.14) will help to limit youth access to the newly deemed tobacco products. In the event that FDA determines that extending the prohibition on self-service displays (§ 1140.16(c)) to the newly deemed products is appropriate and meets the applicable standard in section 906(d), FDA will issue a new NPRM and seek comment.

(Comment 224) Many comments supported the minimum age and identification requirements for covered tobacco products based on increased youth use of newly deemed products and the impact of nicotine on youth. They noted that, according to the CDC, e-cigarette use among youth doubled from 2011 to 2012, with 1.78 million high school and middle school students having ever used e-cigarettes (Ref. 108). Others noted that the 2012 Surgeon General's report stated that youth are more sensitive to developing nicotine dependence than adults (Ref. 49). In addition, other comments stated that because minimum age and identification requirements for covered tobacco products vary among the states, a uniform age requirement would help prevent youth from accessing tobacco products in a neighboring state with less stringent requirements.

(Response) FDA agrees with comments supporting the implementation of minimum age and identification requirements for covered tobacco products. As we noted in the NPRM, the goal of the minimum age restriction is to limit youth access to the newly deemed tobacco products. FDA concludes that the restrictions included with this final deeming rule are appropriate for the protection of the public health because they will reduce youth access to and, therefore, likely limit use of tobacco products.

(Comment 225) Several comments recommended that FDA raise the minimum age to purchase tobacco products to 21 years old. They claimed that a higher minimum age would restrict youth access to social sources of tobacco products because minors tend to have less contact in their social network with 21-year-olds than with 18-year-olds (Ref. 244). They also suggested that the minimum age and identification requirement should mirror the minimum age requirement for alcohol and marijuana purchases in some States.

(Response) FDA has determined that minimum age and identification restrictions, which will apply to all covered tobacco products, are appropriate for the protection of public health. FDA also will continue to provide prevention and tobacco product risk awareness campaigns targeted to youth and young adults. Although section 906(d)(3)(ii) precludes FDA from raising the minimum age of sale of tobacco products, section 104 of the Tobacco Control Act required FDA to conduct a study on the public health implications of raising the minimum age of sale of tobacco products. This study's report was published (Ref. 245) and can be found at: *http://www.iom.edu/Reports/2015/TobaccoMinimumAgeReport.aspx.*

(Comment 226) Several comments discussed Internet sales of tobacco products. Some comments favored a ban on Internet sales for all tobacco products, some supported a ban on only certain tobacco products, and others opposed a ban on Internet sales of any tobacco products.

(Response) As explained elsewhere, under this rule, retailers may not sell covered tobacco products (through any medium, including the Internet) to individuals under 18 years of age. FDA will continue to actively enforce the minimum age restriction for Internet sales. FDA will consider these comments in the future and continue to assess whether additional access restrictions would be appropriate.

(Comment 227) Several comments recommended that FDA impose stiff penalties for noncompliance with minimum age and identification requirements and institute youth tobacco prevention campaigns and other actions to effectively reduce youth access to tobacco products.

(Response) As noted in the NPRM, FDA believes that combining the minimum age and identification restriction with comprehensive and consistent enforcement, both at the Federal level and in partnership with States, will decrease the likelihood of youth smoking initiation (79 FR 23142 at 23161). In addition, FDA will continue to invest in a number of public education campaigns to help educate the public—especially youth—about the dangers of tobacco products.

(Comment 228) Several comments recommended that FDA prohibit the sale of tobacco product components, parts, and accessories (not just covered tobacco products), including ENDS, to minors under 18 years of age to provide consistency across the country.

(Response) FDA disagrees. FDA concludes that the application of minimum age requirements and vending machine requirements to covered tobacco products, together with its regulation of components and parts of newly deemed products, will protect the public from the dangers of tobacco use, discourage initiation, and encourage cessation of use of such products.

(Comment 229) A few comments suggested that FDA prohibit cigar sales to individuals under 18 years of age, except for minors serving in the U.S. military. They argued that there are greater health hazards for military personnel than using tobacco products.

(Response) We disagree with the suggestion that we provide an exception for minors in the military. Military personnel face the same risk of tobacco-related death and disease as civilians. As FDA stated in the preamble, cigars can contain greater levels of nicotine than cigarettes; cigar smoking is strongly related to certain cancers; and in certain circumstances, cigars may be as harmful to a person's health as cigarettes (79 FR 23142 at 23151, 23156).

(Comment 230) Some comments suggested that retailers record and retain copies of each purchaser's unexpired driver's license (if the document includes a photo), an armed forces identification card, or a valid passport as an acceptable identification to verify a purchaser's minimum age. Other comments recommended that FDA implement a registration requirement for mail order sale of tobacco products and require carriers to verify that the seller sending out packages is registered before accepting the packages for delivery.

(Response) The requirements for photo identification are included in § 1140.14(b)(2). Retailers may choose any method of identification verification that complies with this provision. FDA finds that these requirements are appropriate for the protection of the public health and declines to adopt the recommendations for additional requirements at this time. However, we will continue to assess whether additional requirements regarding identification are appropriate.

G. Comments and Responses Regarding Vending Machines

Consistent with the minimum age and identification provisions, FDA proposed to ban the sale of covered tobacco products in vending machines (*i.e.*, requiring face-to-face transactions in retail facilities) unless the vending machine is located in a facility where the retailer ensures that individuals under 18 years of age are prohibited from entering at any time. FDA is finalizing this requirement without change in § 1140.14. Therefore, upon the effective date of this final rule, covered tobacco products, including ENDS and cigars, may not be sold in electronic or mechanical devices such as vending machines unless the device is in an adult-only facility. This restriction is appropriate for the protection of the public health because it will eliminate one more method of youth access to tobacco products.

A summary of the comments regarding these provisions, and FDA's responses to them, is included in the following paragraphs.

(Comment 231) Multiple comments supported restricting vending machines sales to adult-only facilities. They asserted that FDA's discussion of this issue demonstrates that the vending machine restriction serves the stated public health purpose of the regulation. Other comments stated that FDA's rationale for this restriction for cigarettes and smokeless tobacco also applies to the newly deemed tobacco products.

(Response) FDA agrees that there is a public health benefit to limiting vending machines to adult-only facilities. As we stated in the NPRM, studies show that youth are able to access tobacco products in vending machines (79 FR 23142 at 23162). Therefore, the vending machine restrictions are important in preventing youth from gaining access to these products.

(Comment 232) Several comments suggested that FDA prohibit all vending machine sales of all tobacco products.

(Response) FDA disagrees with prohibiting all vending machine sales of all tobacco products. Sections 1140.14(a)(3) and 1140.14(b)(3) permit the sale of cigarettes and smokeless tobacco products and covered tobacco products, respectively, in a non-face-to-face exchange with the assistance of a mechanical device as long as the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time. FDA is permitting adult-only facilities to sell tobacco products in a vending machine because these locations employ safeguards to prohibit entry to individuals less than 18 years of age. FDA is not seeking to ban adult access to legally marketed tobacco products.

(Comment 233) Several comments recommended that FDA subject tobacco product components, parts, and accessories (particularly e-cigarettes) to the proposed vending machine restrictions. These comments expressed concern regarding exploding tanks and nicotine poisoning due to accidental e-liquid exposure.

(Response) FDA agrees that these tobacco product components and parts can pose public health concerns. At this time, FDA has determined that it is appropriate for the protection of the public health to restrict impersonal modes of sale of nicotine-containing components and parts in vending machines. However, FDA has concluded that it is not warranted at this time to impose the vending machine restrictions on components or parts that are not made or derived from tobacco as they will only be able to deliver nicotine to users by combining them with covered tobacco products that are subject to the vending machine restriction (and, therefore, youth cannot access). Accordingly, FDA believes that the public health will be protected by applying the vending machine restrictions to components and parts that contain nicotine or tobacco in order to prevent youth access to these products.

(Comment 234) Some comments suggested that the deeming rule include a ban on Internet sales. These comments asserted that manufacturers and retailers are not enforcing age verification effectively and that youth are able to purchase tobacco products when they are not in the physical presence of the seller. Several comments also recommended that FDA require retailers to verify the age of purchasers of newly deemed tobacco products using methods similar to those found in the Prevent All Cigarette Trafficking (PACT) Act of 2009 (which ensures the collection of Federal, State, and local tobacco taxes on cigarettes and smokeless tobacco sold via the Internet or mail order sales). Other comments opined that neither the PACT Act nor State laws have been effective in preventing youth access to tobacco products.

(Response) Under this rule, retailers may not sell covered tobacco products (through any medium) to individuals under 18 years of age. FDA will continue to actively enforce the minimum age restriction for mail order sales and Internet sales. FDA will continue to assess whether additional access restrictions would be appropriate.

(Comment 235) A few comments stated that because newly deemed tobacco products are generally not sold in vending machines, there will be little impact from the proposed vending machine restrictions.

(Response) FDA disagrees. As discussed in the NPRM (79 FR 23142 at 23162), FDA expects that the vending machine restrictions will have a positive impact by preventing some youth from accessing tobacco products. Therefore, FDA concludes that this restriction is appropriate for the protection of the public health.

(Comment 236) A few comments stated that FDA should permit tobacco product sales through vending machines in all locations. They noted that technological advancements now allow for accurate non-face-to-face age verification, including electronic age and identity verification (EAIV) technology and that the PACT Act already requires retailers to verify a tobacco product purchaser's name, birth date, and address through an EAIV database prior to accepting a delivery order.

(Response) FDA disagrees. We explained in the NPRM that other types of vending machine restrictions, such as electronic locking devices on vending machines, have not sufficiently limited youth access to tobacco products (79 FR 23142 at 23162). In addition, vending machines may be located in facilities that are not as sophisticated as the common carriers or Internet sellers that are subject to the PACT Act, or these retailers may not have the financial resources to update their vending machines to incorporate EAIV technology. Therefore, FDA concludes that the vending machine restriction is appropriate for the protection of public health.

XVI. Description of the Final Rule—Part 1143

In the proposed deeming rule, FDA proposed to add part 1143, which would mandate the use of "required warning statements" for covered tobacco products, as well as for roll-your-own and cigarette tobacco, for which health warnings are not already required by Federal statutes or regulations. As stated throughout this document, FDA has selected Option 1 with this final rule. Therefore, these requirements apply to all newly deemed covered tobacco products, including premium and other types of cigars. We consider and intend the extension of our authorities over tobacco products and the various requirements and prohibitions established by this rule to be severable.

A. Section 1143.1—Definitions

In the NPRM, FDA sought comment on definitions for the following terms: Cigar, covered cigar, covered tobacco product, package, required warning statement, and roll-your-own tobacco. As stated throughout this document, FDA has selected Option 1 as the scope of this rule. Therefore, the definition of covered cigar is unnecessary and has been removed from this section. We also added definitions of point-of-sale, retailer, and tobacco product. These terms are used in part 1143 and were already included in parts 1100 and 1140.

FDA received many comments regarding the need to define components, parts, and accessories, which resulted in the addition of definitions of "component or part" and "accessory" in § 1140.3. The discussion of this language in included in section VI.A. In addition, we included a definition of "cigarette tobacco" given that the health warning requirements apply to covered tobacco products, roll-your-own tobacco, and cigarette tobacco. We also have added a definition of "principal display panels" to address comments suggesting that a definition was necessary to comply with this part. The term "principal display panels" is defined as the panels of a package that are most likely to be displayed, presented, shown, or examined by the consumer.

B. Section 1143.3—Required Warning Statement Regarding Addictiveness of Nicotine

Proposed § 1143.3 included a requirement that any person who manufactures, sells, offers to sell, distributes, or imports for sale or distribution within the United States, cigarette tobacco, roll-your-own tobacco and covered tobacco products other than cigars must include the following warning statement on each product package and in each advertisement: "WARNING: This product contains nicotine derived from tobacco. Nicotine is an addictive chemical." The NPRM provided that a manufacturer could submit a certification that its tobacco product does not contain nicotine and notify FDA that it intends to use the alternative warning statement: "This product is derived from tobacco." FDA also proposed size and placement requirements for the use of this warning statement on packages and in advertisements.

Upon review of the comments, FDA is revising the language of this warning to read: "WARNING: This product contains nicotine. Nicotine is an addictive chemical." The alternative warning statement is also revised to read: "This product is made from tobacco." This warning will be required to appear on at least 30 percent of the two principal display panels of the package and at least 20 percent of the area of the advertisement. We also added language to § 1143.3(a) to clarify that the warning statement must be printed in at least 12-point font size in order to be clear and legible.

Further, we added language to § 1143.3(a)(3)(ii) to clarify when a retailer of any tobacco product covered by paragraphs (a)(1) and (2) of this section will not be in violation of this section for packaging that does not comply with these requirements. This final rule provides that a retailer will not be in violation if the package: (1) Contains a health warning; (2) is supplied to the retailer by a tobacco product manufacturer, importer, or distributor, who has the required state, local, or TTB-issued license or permit, if applicable (consistent with the language in § 1143.5(a)(4)(ii)); and (3) is not altered by the retailer in a way that is material to the requirements of this section.

In addition, in response to comments regarding minimum font size for advertisements, we have revised § 1143.3(b)(2)(ii) to include a 12-point minimum font size for the warnings on advertisements. We note that the warning also needs to occupy "the greatest possible portion of the warning area set aside for the required text." Therefore, a print advertisement would require a much larger font size in order to comply with this requirement.

Given that comments expressed uncertainty as to how the self-certification process in § 1143.3(c) would work, we also included language in this section to further clarify this process. This section now provides that the certification statement can be submitted by the tobacco product manufacturer to FDA. FDA recommends that all data used to support the self-certification, or copies of the data, be maintained at the manufacturing facility or another location that is reasonably accessible to the manufacturer and to any officers or employees duly designated by the Secretary, which includes FDA employees. These data, including data not stored at the inspected facility, should be made readily available for copying or inspection by an officer or employee duly designated by the Secretary. Manufacturers interested in submitting a certification statement may contact CTP at 1–877–CTP–1373 for more information regarding this submission.

Further, in response to comments, we added § 1143.3(d), which states that, if a product package is too small or otherwise unable to accommodate a label with sufficient space to bear such information, it will be exempt from the requirement to place the warning statement directly on the product package if the warning appears on the outer carton or other outer container or wrapper or on a tag otherwise permanently affixed to the tobacco product package. Under this provision, the warning statement must be printed using the specifications required in § 1143.3(a)(1) and (a)(2). In these cases, the outer carton, outer container, wrapper, or tag would serve as the location for the principal display panels. If a tag is used for the principal display panels, both sides of the tag must be visible to the consumer. The warning statements must be printed on both sides of the tag to comply with § 1143.3(a)(2).

We also note that this requirement in § 1143.3 applies to cigarette tobacco, roll-your-own tobacco, and covered tobacco products other than cigars. Both cigarette tobacco and roll-your-own tobacco are defined in § 1143.1. This warning requirement does not apply to smokeless tobacco products. Smokeless tobacco products must meet the warnings requirements in CSTHEA (15 U.S.C. 4401 *et seq.*).

C. Section 1143.5—Required Warning Statements for Cigars

In § 1143.5, FDA proposed warnings for the cigars that would be covered under this final rule. In addition to the addictiveness warning, FDA proposed that all cigars (except those sold individually and not in product packages) would be required to include the following warnings on packages and in advertisements:

- WARNING: Cigar smoking can cause cancers of the mouth and throat, even if you do not inhale.
- WARNING: Cigar smoking can cause lung cancer and heart disease.
- WARNING: Cigars are not a safe alternative to cigarettes.
- WARNING: Tobacco smoke increases the risk of lung cancer and heart disease, even in nonsmokers.

FDA also proposed size and placement requirements for the warning statements on packages and in advertisements. FDA is finalizing these warning requirements in accordance with Option 1 deeming all cigars (rather than a subset). Further, FDA is adding an additional warning statement (WARNING: Cigar use while pregnant can harm you and your baby.) with an optional alternative statement (SURGEON GENERAL WARNING: Tobacco Use Increases the Risk of Infertility, Stillbirth and Low Birth Weight) as discussed in section XVI.H.16.

Therefore, the full list of required warnings for use on cigar packages and in cigar advertisements is as follows:

- WARNING: This product contains nicotine. Nicotine is an addictive chemical.
- WARNING: Cigar smoking can cause cancers of the mouth and throat, even if you do not inhale.
- WARNING: Cigar smoking can cause lung cancer and heart disease.
- WARNING: Cigars are not a safe alternative to cigarettes.
- WARNING: Tobacco smoke increases the risk of lung cancer and heart disease, even in nonsmokers.
- WARNING: Cigar use while pregnant can harm you and your baby. (Or, as an optional alternative statement: SURGEON GENERAL WARNING: Tobacco Use Increases the Risk of Infertility, Stillbirth and Low Birth Weight.)

The health warnings are required to appear on at least 30 percent of each of the two principal display panels of the package and on at least 20 percent of the area of the print advertisements and other advertisements with a visual component. As we did for § 1143.3(a)(2)(ii) and (b)(2)(ii), we added language to § 1143.5(a)(2)(ii) and (b)(2)(ii) to clarify that the font used for warnings on packaging and advertisements must be at least 12-point font size in order to be clear and legible. We note that the warning also must occupy "the greatest possible portion of the warning area set aside for the required text." Therefore, a print advertisement would require a much larger font size in order to comply with this requirement.

For packages, the six warnings for cigars (five specifically for cigars and the one addictiveness warning) will be required to be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of cigar sold in product packaging and randomly distributed in all areas of the United States. This random display and distribution must be done in accordance with a warning plan submitted to, and approved by, FDA. For advertisements, the warnings must be rotated quarterly in alternating sequence in each advertisement for each brand of cigar in accordance with a warning plan submitted to, and approved by, FDA. Warning plans must be submitted for FDA review and approval by responsible manufacturers, distributors, importers, and retailers by 1 year after the date of publication of the final rule (however, all other part 1143 requirements shall take effect 2 years after the publication date of this final rule).

In the NPRM, FDA did not have a separate section (with its own effective date) explicitly requiring the submission of warning plans with its own effective date. Rather, the sections of part 1143 requiring random display and distribution of warning statements for packaging and quarterly rotation of warning statements for advertisements (for which FDA proposed a 2-year effective date) stated that such random display and distribution and quarterly rotation be done in accordance with a warning plan submitted to and approved by FDA. Thus, those provisions implicitly required that submission of the warning plan and approval by FDA be done prior to the 2-year effective date by which manufacturers must comply with the plan. FDA has added § 1143.5(c)(3) to specifically include the requirement to submit a proposed warning plan. (See section XVI.H.17 for additional information regarding the warning plan requirement and timeframe for submission.)

The same warning statement requirements will apply to cigars sold individually and not in product packages.[15] However, instead of being required to place warnings directly on these product packages, retailers will be required to post signage at the point of sale listing the six warnings (five specifically for cigars and one addictiveness warning) on a minimum of 8.5 x 11 inch sign. The rule requires that the sign be placed on or within 3 inches of each cash register where payment is made and the sign is unobstructed in its entirety and can be easily read by each consumer making a purchase.

D. Section 1143.7—Language Requirements for Required Warning Statements

Consistent with section 3(b) of CSTHEA (15 U.S.C. 4402(b)), FDA proposed in § 1143.7 that the warning statement appear in the English language, with two exceptions. First, under § 1143.7(a), if an advertisement appears in a non-English language publication, the required warning statement would be required to appear in the predominant language (*i.e.*, the primary language used in the nonsponsored content) of the publication. Second, under § 1143.7(b), if an advertisement is in an English language publication but the advertisement is presented in a language other than English, the required warning statement would be required to appear in the same foreign language as that principally used in the advertisement. FDA is finalizing this section as proposed in the NPRM with one change; given that FDA has noted throughout this document that the health warning requirements apply to advertisements in any medium, we have changed the references from "publication" to "medium" in this section.

E. Section 1143.9—Irremovable or Permanent Required Warning Statements

FDA proposed that the warning statements for covered tobacco products be indelibly printed on or permanently affixed to packages and advertisements. FDA is finalizing this requirement without change.

F. Section 1143.11—Does Not Apply to Foreign Distribution

FDA proposed to limit the applicability of the health warning requirements by clarifying that they would not apply to manufacturers or distributors of tobacco products that do not manufacture, package, or import the products for sale or distribution within the United States. FDA is finalizing this requirement.

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[15] In general, pursuant to the Internal Revenue Code at 26 U.S.C. 5751, a tobacco product cannot be sold at retail unless it is in the package in which the product is removed, upon payment of Federal excise tax, from the factory or from customs custody. Section 5751(a)(3) and TTB regulations at 27 CFR 46.166(a) state that tobacco products may be sold, or offered for sale, at retail from such packages, provided the products remain in the packages until removed by the customer or in the presence of the customer.

G. Section 1143.13—Effective Date

In the NPRM, FDA sought comment regarding the effective date of the health warning requirements. FDA proposed that these requirements would take effect 24 months after the date that the final rule publishes in the **Federal Register** and all products manufactured on or after the effective date must include the required warning statements on their labels.

This means that:

- After the effective date, no manufacturer, packager, importer, distributor, or retailer of cigarette tobacco, roll-your-own tobacco, cigars, or other covered tobacco products may advertise any such product if the advertisement does not comply with this rule;
- After the effective date, no person may manufacture for sale or distribution within the United States any such product the package of which does not comply with this rule;
- Beginning 30 days after the effective date, a manufacturer may not introduce into domestic commerce, any such product, irrespective of the date of manufacture, if its package does not comply with this rule;
- After the effective date, a distributor or retailer may not sell, offer to sell, distribute, or import for sale or distribution within the United States any such product the package of which does not comply with this regulation, unless the covered tobacco product was manufactured prior to the effective date; and
- After the effective date, however, a retailer may sell covered tobacco products in packages of which do not have a required warning if the retailer demonstrates it falls outside the scope of this rule as described in §§ 1143.3(a)(3) and 1143.5(a)(4).

In addition to proposed § 1143.13, we added paragraph (b) indicating that the requirement to submit a warning plan pursuant to § 1143.5(c)(3), describing the random display and distribution of warning statements on cigar packages and the quarterly rotation of warning statements in cigar advertisements, will take effect 12 months after the date of publication of this final rule. FDA is establishing this effective date at 12 months before the effective date of the required warnings for cigars described under part 1143 (24 months after the publication of the final rule) because the Agency anticipates that there will be a need for communication with submitters during its review of the warning plan submissions. This submission deadline also helps FDA to ensure that its surveillance program for compliance with the warning label requirements under section 1143 is implemented as of the effective date of 24 months after the publication of the final rule. FDA intends to work with manufacturers, importers, distributors, and retailers to get an approved warning plan in place. Cigar entities may wish to contact FDA to discuss the submission of their warning plans in order to make the subsequent approval process more orderly and efficient. See section XVI.H.17 for additional information regarding the warning plan requirement.

H. Comments and Responses Regarding Required Warning Statements

1. General

(Comment 237) Several comments urged FDA to clearly define "advertisement" in the final rule as it is unclear what constitutes an advertisement that must contain the required warning statements. At least one comment suggested that the final rule contain language explaining that any statement regarding the availability of tobacco products in a store does not by itself constitute an advertisement.

(Response) FDA does not believe it is necessary to include a definition of "advertisement" in this final rule, but notes that for purposes of this rule, the term "advertisement" should be interpreted broadly and should be interpreted to include statements regarding the availability of tobacco products.

In addition, advertisements subject to this final rule may appear in or on, for example, promotional materials (point-of-sale or non-point-of-sale), billboards, posters, placards, published journals, newspapers, magazines, other periodicals, catalogues, leaflets, brochures, direct mail, shelf-talkers, display racks, Internet Web pages, television, electronic mail correspondence, and also include those communicated via mobile telephone, smartphone, microblog, social media Web site, or other communication tool; Web sites, applications, or other programs that allow for the sharing of audio, video, or photography files; video and audio promotions; and items not subject to the sale or distribution ban in § 1140.34. FDA intends to provide guidance on how to comply with the health warning requirements on unique types of media.

(Comment 238) Several comments noted that the proposed cigar warnings are appropriate for the protection of public health. The comments noted that the rule would enhance public health by extending the labeling requirements beyond the seven manufacturers currently required to use them under the FTC consent decrees, by providing for random display on cigar packages and rotation in advertisements, and by requiring point-of-sale warnings for cigars sold individually that are not packaged. The comment also noted that the substance of each warning is strongly supported by the available scientific evidence. However, several comments took issue with the proposed warnings for premium cigars, claiming that they lack a sound scientific basis.

(Response) FDA finds there is a strong scientific basis to require health warnings on cigar packages and in cigar advertisements (as well as on signs for unpackaged cigars), which was extensively discussed in the NPRM (79 FR 23142 at 23167 through 23170).

(Comment 239) Several comments stated that the NPRM is unclear regarding the requirement to develop and submit rotation plans for warnings signs required where cigars are sold individually and not in a product package. One comment stated that the final rule should make clear that this obligation falls on cigar manufacturers and not on retailers that sell cigars. Another comment stated that retailers should be responsible for creating and posting the point of sale signs.

(Response) To clarify, retailers of cigars sold individually and not in product packaging are not required to submit a warning plan for warnings on packages, because the warning signs posted at a retailer's point-of-sale would include all six warnings applicable to cigars, as we have noted above in our discussion of § 1143.5(c)(1). Cigar retailers would be responsible for creating and posting these signs in accordance with § 1143.5(a)(3)(i)–(iv). Therefore, there is no need to rotate these health warnings, nor is it necessary to submit a rotational warning plan for them. However, manufacturers must submit a warning plan for advertisements, as the rule requires manufacturers of *all* cigars to include warnings in advertisements that must be rotated quarterly in alternating sequence in each advertisement for each brand of cigar. Similarly, retailers who are responsible for or direct their own cigar advertising must submit a warning plan for those advertisements.

(Comment 240) One comment suggested that FDA adopt labeling rules, similar to those proposed for premium cigars, for e-cigarette products that are sold without packaging (*i.e.*, require signage at the point of sale for stores selling e-cigarettes rather than require labels on their packages).

(Response) Unlike cigars sold individually and not in product packages, ENDS and any e-liquids containing nicotine that are sold separately are sold in some sort of packaging on which the addictiveness warning can be provided. Therefore, it is not necessary at this time to instead require warnings at the point-of-sale. The warning requirements in this final rule are appropriate for the protection of the public health because they provide information to the consumers each time they use the product.

2. Continuum of Risk

(Comment 241) Several comments asserted that different product categories should carry different health warnings relative to the health risk the products present to adult consumers. They also thought that, in view of the continuum of risk, the size of the proposed addictiveness warning on e-cigarettes and other noncombusted products is too large and the location too prominent. For example, one comment suggested that FDA require that this warning be smaller for these products than for smokeless tobacco products (*i.e.*, 20 percent of the principal display panel) and it should appear only on one of the principal display panels of the package. Another comment noted that, because of its relative size and placement, the proposed e-cigarette warning could deter combusted cigarette smokers from switching to a noncombusted product based on a misunderstanding of the relative risks of smoking versus electronic and noncombusted products. This comment suggested that the warning on e-cigarettes should be no larger or more prominently located than the currently required cigarette warnings.

(Response) FDA disagrees. As discussed in section VIII, though FDA recognizes the existence of a continuum of nicotine-delivering products, all tobacco products are addictive and potentially dangerous. There is a public health benefit to warning consumers regarding the addictiveness of nicotine, regardless of how it is delivered. Numerous studies show that the likelihood that warnings are seen and noticed depends upon their size and position. (Refs. 36, 37, 38, 39; see section II.B.4). In addition, as mentioned in section VIII.C, study results have been inconclusive about the effects of ENDS products on the population. FDA does not believe, at this time, that it has sufficient evidence about the risks of ENDS products to justify the use of different warnings sizes and to determine the appropriate size for each product category. FDA will continue to monitor research regarding the health effects of different types of ENDS.

As to the comment that e-cigarette warnings should be no larger or more prominently located than currently required for cigarettes, the final rule requires the warnings to appear on at least 30 percent of the two principal display panels of the package, and at least 20 percent of the area of advertisements. These are the same warning sizes that Congress established for smokeless tobacco in the Tobacco Control Act. 15 U.S.C. 4402(a)(2)(A), (b)(2)(A). In the same Act, Congress prescribed an even larger size for cigarette warnings: 50 percent on the front and rear panels of cigarette packaging (and the same 20 percent size for cigarette advertisements) (id. § 1333(a)(2), (b)(2)). However, the larger warning sizes required for cigarettes have not yet been implemented because the final rule was challenged in court, and on August 24, 2012, the United States Court of Appeals for the District of Columbia Circuit vacated the rule and remanded the matter to the Agency. *R.J. Reynolds Tobacco Co.*, v. *Food & Drug Administration*, 696 F.3d 1205 (D.C. Circuit 2012), *overruled on other grounds by Am. Meat Inst.* v. *U.S. Dep't of Agric.*, 760 F.3d 18, 25 (D.C. Cir. 2014) (*en banc*). On December 5, 2012, the Court denied the government's petition for panel rehearing and rehearing en banc, and FDA decided not to seek further review of the Court's ruling. FDA is conducting research that aims to support a new rulemaking consistent with the Tobacco Control Act (see Generic Clearance for the Collection of Qualitative Data on Tobacco Products and Communications (OMB Control Number 0910–0796) and Pretesting of Tobacco Communications (OMB Control Number 0910–0674)). For smokeless tobacco packaging, the warning labels must be located on the two principal display panels and cover at least 30 percent of each panel (15 U.S.C. 4402(a)(2)(A)), which is consistent with the warning labels required for newly deemed tobacco products.

(Comment 242) Several comments stated that informing consumers that tobacco products are addictive by requiring an addictiveness warning does not fulfill any useful public health goal. These comments believed that it is misleading to describe all nicotine-containing products as addictive without describing the relative risk of the products.

(Response) FDA disagrees. The addictive nature of tobacco products has been well documented. The Surgeon General has long recognized the addictive nature of tobacco products due to the presence of nicotine, which is highly addictive and can be absorbed into the bloodstream (Ref. 1). Congress also expressed concern about the addictiveness of these "inherently dangerous products" (section 2(2) of the Tobacco Control Act). Because the covered tobacco products are made or derived from tobacco and most (if not all) contain nicotine, they are likely addictive (Refs. 14, 246, 247, 248, 249). For products that do not contain nicotine (*i.e.*, no nicotine at detectable levels), the rule provides for an alternative warning statement, "This product is made from tobacco."

Consumers, especially youth and young adults, wrongly believe that many tobacco products covered by this rule are less addictive than cigarettes; systematically underestimate their vulnerability to becoming addicted to nicotine and the use of tobacco products; and overestimate their ability to stop using tobacco products when they choose (79 FR at 23158–59, 23166). The addictiveness warning will help consumers understand and appreciate the consequences of using tobacco products. The addictiveness warning will help ensure that youth and young adults, who may be more susceptible to the addictiveness of nicotine, have a greater awareness of the presence of nicotine and the addictiveness of these products before they might become addicted.

Additionally, any manufacturer that wishes can submit an MRTP application to FDA to show that its product is less hazardous than another tobacco product. When the Tobacco Control Act was passed, Congress found that unless tobacco products that purport to reduce the risks to the public of tobacco use actually reduce such risks, those products can cause substantial harm to the public health (section 2(37) of the Tobacco Control Act). Furthermore, Congress noted that the dangers of products sold or distributed as MRTPs that do not in fact reduce risk are so high that FDA must ensure that statements about MRTPs are complete, accurate, and relate to the overall disease risk of the product (section 2(40) of the Tobacco Control Act). Accordingly, Congress determined that manufacturers must demonstrate that such products meet a series of rigorous criteria, and will benefit the health of the population as a whole before they may be marketed to reduce the harm or the risk of tobacco-related disease or to reduce exposures to harmful substances associated with tobacco products (section 911 of the FD&C Act (21 U.S.C. 387k)). If new research on the relative risks presented by the use of smokeless tobacco products and ENDS products emerges, FDA may consider proposing changes to the warning label requirements. If it does, the Agency will initiate a new rulemaking in accordance with the APA.

3. Warning Requirements for Other Media

(Comment 243) Several comments stated that FDA should clarify the application of the proposed warnings to television and radio advertisements, as well as in catalogs, on Internet sites, and on social media. One comment recommended that advertisers be required to include a voiceover stating the warning out loud, in a clear, conspicuous, and neutral manner. Another comment suggested that FDA clarify in the final regulation that § 1143.3(b) applies only to print advertising and not to radio and broadcast advertising.

(Response) FDA clarifies that § 1143.3(b)(1) applies to cigarette tobacco, roll-your-own tobacco, and covered tobacco products except for cigars as they have their own warning requirements as enumerated in § 1143.5(b)(1). The FCLAA (15 U.S.C. 1331 *et seq.*), as modified by the Little Cigar Act of 1973 (Pub. L. 93–109), makes it unlawful to advertise "cigarettes" and "little cigars" on any medium of electronic communication subject to the jurisdiction of the Federal Communications Commission (15 U.S.C. 1333). In 1986, Congress enacted CSTHEA (15 U.S.C. 4401 *et seq.*), extending the broadcast ban to include advertisements for smokeless tobacco products.

FDA further clarifies that the requirements to include a warning in § 1143.3(b)(1) and § 1143.5(b)(1) apply to all forms of advertising, regardless of the medium in which it appears, for cigarette tobacco, roll-your-own tobacco, and covered tobacco products, including cigars. This final rule applies to advertisements appearing in or on, for example, promotional materials (point-of-sale and non-point-of-sale), billboards, posters, placards, published journals, newspapers, magazines, other periodicals, catalogues, leaflets, brochures, direct mail, shelf-talkers, display racks, Internet Web pages, television, electronic mail correspondence, or be communicated via mobile telephone, smartphone, microblog, social media Web site, or other communication tool; Web sites, applications, or other programs that allow for the sharing of audio, video, or photography files; video and audio promotions; and items not subject to the sale or distribution restriction in § 1140.34. Accordingly, the language of §§ 1143.3(b)(2) and 1143.5(b)(2) have been changed to clarify that the formatting requirements only apply to print advertisements and other advertisements with a visual component. FDA intends to provide guidance on how to comply with the health warning requirements on unique types of media.

4. Appropriateness of Required Warnings To Protect Public Health

(Comment 244) In response to FDA's request in the NPRM, comments included data and research regarding the effectiveness of health warnings. They submitted research indicating a need for accurate health warnings that are large enough to be readable (Refs. 3, 40) and grab the consumer's attention (Ref. 40). Comments also submitted research indicating that warning labels influence and increase awareness of the health risks associated with tobacco (Ref. 36, 37, 250) and discourage initiation in nonsmoking youth (Ref. 251). One comment cited other research which found that novel information presented to smokers was associated with greater relevance of the message and motivation to quit (Ref. 252).

(Response) FDA agrees that health warnings are an effective means to help consumers understand and appreciate the risks of using tobacco products.

(Comment 245) Many comments supported the requirement for all tobacco products to contain health warnings. For example, one comment cited WHO's 2011 report on the Global Tobacco Epidemic, which states that effective warning labels increase smokers' awareness of health risks and increase the likelihood they will think about reducing tobacco consumption and quitting (Ref. 253). The comment also cited a cohort study of textual warnings in the United Kingdom, before and after they were enhanced in 2003 to meet the minimum FCTC standard (Ref. 37). This study found that, after the enhanced warnings were implemented, UK smokers were more likely to think about quitting, to think about the health risks of smoking, and to be deterred from having a cigarette compared to smokers in Australia and the United States where smaller warnings did not conform to FCTC standards. Another comment stated that required warning statements on packages and advertisements should provide needed information to consumers in a conspicuous and clear manner.

(Response) FDA agrees. Health warnings on packages and advertisements help consumers to understand and appreciate the health risks of tobacco use and have a number of advantages. The frequency of exposure is high. In addition, package warnings are delivered both at the time of tobacco product use and at the point of purchase. Thus, the messages are delivered to tobacco users at the two most important times—when users are considering using or purchasing the tobacco product. The messages on packages also help the public at large, including potential tobacco users, better understand and appreciate the health and addictiveness risks of using the products. (See In re Lorillard et al., 80 FTC 455 (1972); FCLAA; CSTHEA.)

5. Staleness of Warnings

(Comment 246) Several comments noted that requiring only a single health warning for some newly deemed tobacco products does not allow for rotation and the warning will likely grow stale, resulting in little to no effect on consumers. They argued that FDA should require multiple warnings for the newly deemed products to allow for rotation and to maintain their effectiveness. Additionally, comments urged FDA to revise this warning and the other required health warnings as new evidence emerges on the health risks associated with tobacco products.

(Response) FDA acknowledges that the use of a single health warning for some newly deemed tobacco products could allow the warning to grow stale over time. While FDA declines to add additional warnings at this time, FDA issued an ANPRM prior to this deeming rule, seeking comments, data, research, or other information that may inform regulatory actions FDA might take with respect to nicotine exposure warnings. FDA also intends to conduct research and keep abreast of scientific developments regarding the efficacy of the final health warnings and the ways in which their efficacy could be improved. FDA will use the results of this monitoring and research to help determine whether any of the warning statements should be revised, or if any additional warning statements should be added, in a future rulemaking.

6. Other Format Issues

(Comment 247) There were several comments on the general format of the health warnings. One comment stated that the warning provisions should require black text on a bright yellow background. According to the comment, researchers have found that yellow seizes attention, is the most noticeable, is the color the eye perceives fastest, and universally signals warning or danger (Refs. 254, 255). Another comment suggested that the front of the package should include a short and explicit warning statement that is large enough to be readily visible and readable, and the back of the package should contain a warning large enough to more fully develop the basis for the front warning statement. The comment noted that the combination of short and salient health claims on the front of the package with more fully developed health information on the back would produce better consumer awareness and understanding, and greater believability of the health claim in the mind of the consumer. Finally, several comments stated that newly deemed products should be required to display large graphic warnings.

(Response) FDA declines to make these suggested changes at this time. The format requirements included with this final rule are similar to those included in a 2001 EU directive, which have been shown to increase the effectiveness of health warnings. EU Directive 2001/37/EC requires that tobacco warnings in all member countries meet certain minimum standards that are similar to those that FDA is finalizing here (*i.e.*, the EU required health warnings comprise 30 percent of the area on the front of package and 40 percent on the back of the package; are in black Helvetica bold type on a white background; occupy the greatest possible proportion of the warning area set aside for the text required; and messages are centered in the warning area and surrounded by a black border of 3 to 4 millimeters (mm) in width). Before the 2001 Directive, warnings in most EU countries were very small and general. In one study conducted for the European Commission, a majority of respondents stated that the Directive's new warning format was more effective and more credible than the previous format (Ref. 256). A study of Spanish university students also concluded that text warnings based on the Directive significantly increased perceptions of the risk of tobacco products (Ref. 257). Additionally, studies showed that the requirement that the warnings appear in black text on a white background or white text on a black background improved the legibility and noticeability of the warnings (Refs. 7, 38).

FDA believes that the prescribed format of the health warnings will be effective in helping consumers better understand and appreciate the risks of these products. However, FDA intends to conduct research and keep abreast of scientific developments regarding the efficacy of the final health warnings and the ways in which their efficacy could be improved. If FDA determines that modification of the format requirements is appropriate, we will consider changing these requirements in a future rulemaking.

(Comment 248) FDA received a large number of comments regarding the size of the required health warnings. Several comments agreed with the format requirements proposed in the rule. One comment cited a study concluding that youth and adults are more likely to recall larger warnings, rate larger warnings as having greater impact, and often equate the size of the warning with the magnitude of the risk (Ref. 36). The comment also stated that requiring health warnings that cover at least 30 percent of the front and back of cigarette packages is consistent with the FCTC.

Several comments argued that the required health warnings are too large. One comment stated that if the warnings are too large, they could have the unintended effect of making consumers numb to the warning message or otherwise lead to consumers ignoring the warning. Another comment stated that the size of FDA's proposed addictiveness warning should be evaluated in the context of the other information that already appears on the packaging of noncombusted tobacco products. This comment asserted that packaging for certain newly deemed products includes detailed warnings and other information important to reduce risks from inappropriate use or handling of the product and that such information may not fit on the package if the proposed health warning occupies 30 percent of the principal display.

Several comments stated that the proposed warning statement should not be required on cigars sold individually and not in product packages. One cigar retailer stated that requiring warnings on 30 percent of the principal display panels would be excessive. The comment believed that a health warning covering 30 percent of each cigar box would be excessive when there are multiple boxes, particularly when combined with the requirement for a warning sign at the point of sale. Another comment asserted that the size of the proposed health warnings would be inconsistent with the First Amendment.

Other comments argued that FDA should require larger health warnings. One comment stated that numerous studies show that youth and adults are more likely to recall larger warning messages and rate larger messages as having a greater impact (Ref. 37). Another comment stated that the FCTC suggests that warnings should cover 50 percent or more of a pack's principal surface, a standard adopted by a number of countries.

(Response) FDA finds that the required size of the health warnings is appropriate for the protection of public health. The IOM, Congress, and Article 11 of the FCTC recognize the importance of having the warnings cover at least 30 percent of the area of the principal display panels, and users are more likely to recall warnings that are a larger size and that appear on the front/major surfaces of the tobacco package (Ref. 7). The 30-percent warning label area requirement for product packages is also consistent with the size requirements for similar text-only warnings for smokeless tobacco mandated by Congress in CSTHEA (15 U.S.C. 4402(a)(2)(A)). FDA does not believe that the 30-percent warning label area requirement will make consumers numb to the warning message. Rather, FDA believes that the size of the warnings will be effective in helping consumers better understand and appreciate the critical information presented by the health warning.

FDA also believes that the 30-percent warning label area requirement is consistent with the First Amendment (as discussed in section II.B). Although the warning will occupy at least 30 percent of the packaging, there will remain sufficient space for additional warnings, manufacturer instructions, and branding. However, FDA intends to conduct research and keep abreast of scientific developments regarding the efficacy of the health warnings in the final rule and the ways in which their efficacy could be improved. If FDA determines that larger warnings would be more effective for these newly deemed products, the Agency will issue a new NPRM in accordance with the APA.

(Comment 249) Comments stated that FDA should not require manufacturers to use a font size that occupies the greatest possible proportion of the warning area because that would leave limited, if any, white space and may prove to be illegible. These comments suggested that FDA reduce the font size requirement to be consistent with smokeless tobacco warnings, which are required to take up 60 to 70 percent of the warning area.

(Response) FDA disagrees. Newly deemed tobacco products are sold in a variety of packaging sizes. By requiring the font size to be at least 12-point font, FDA is ensuring that the required warning statement will be noticed by consumers regardless of the package size. Further, FDA believes that this requirement will leave adequate background space so that the warning is legible. The format requirements are similar to those included in a 2001 EU directive (requiring warnings to occupy the greatest possible portion of the warning area set aside for the required text), which have been shown to increase the effectiveness of health warnings, as further discussed in this section of the document. FDA is not aware of any legibility issues with the EU health warnings and does not expect any legibility issues with the health warnings included in this final rule.

The size of the warning clearly matters, as recall increases significantly with font size (Ref. 258). In a study on recall of health warnings in smokeless tobacco ads, conducted with 895 young males, 63 percent of participants recalled a high contrast warning in 10-point font; doubling the font size for the warning to a 20-point font increased recall from 63 percent to 76 percent representing a 20 percent improvement in recall (id.). Research on cigarette package warnings confirms that larger warnings are better noticed and more likely to be recalled (Ref. 7 at App. C–3; Refs. 38, 49). These studies support FDA's conclusion that requiring the proposed warnings to appear in at least 12-point font size will improve their noticeability.

(Comment 250) At least one comment believed that requiring warnings to occupy at least 20 percent of the area of an advertisement would result in warning statements that, while visible, are more likely to be ignored. This comment suggested that appropriate warning statements be presented in a minimum font size (*e.g.*, no smaller than 11-point type).

(Response) FDA is unaware of any evidence stating that a health warning occupying at least 20 percent of the area of an advertisement is likely to be ignored. Nevertheless, to ensure that the statements are visible and effectively conveying information, FDA is finalizing §§ 1143.3(b)(2)(ii) and 1143.5(b)(2)(ii) to require a minimum 12-point font size for the health warnings on advertisements. Moreover, the requirement that the warning statement occupy at least 20 percent of the area of the advertisement is the same as the statutory requirement for press and poster advertisements for smokeless tobacco products (section 3(b)(2)(B) of CSTHEA (15 U.S.C. 4402(b)(2)(B))).

(Comment 251) At least one comment expressed concern with the font requirements of the labeling provisions because they require businesses to purchase a software package that provides either or both of the prescribed fonts (Helvetica and Arial), and these are proprietary fonts.

(Response) FDA disagrees. Both Helvetica and Arial fonts are included in common printing software. Thus, the requirement that manufacturers use Helvetica or Arial font should not cause them to incur any additional costs. However, we also have included language throughout part 1143, which allows manufacturers to use other similar sans serif fonts in order to provide additional flexibility while still ensuring that the warnings are conspicuous and legible to consumers.

(Comment 252) Many comments argued for different formatting requirements for the health warnings. Some suggested that they should be consistent with the current FTC Consent Decree, which requires that health warnings be clear and conspicuous in relation to the other communications on the packaging and be presented in a black box format to attract consumer attention. One comment stated that FDA should accept alternative warning sizes, placements, and font sizes for different packaging sizes and configurations, as long as the warning is clear and conspicuous. This comment urged FDA to be flexible about the size and placement of the warnings on deemed products, some of which are offered in packaging sizes and configurations very different from cigarette and smokeless tobacco packaging. This comment also noted that it can be difficult to identify the two principal display panels.

(Response) FDA disagrees. FDA has concluded that the formatting requirements for the health warnings, which are similar to the requirements for smokeless products and similar to those suggested by FCTC, are appropriate for the protection of the public health. In addition, we have added language to this final rule which recognizes that if a product package is too small to bear the required warning statement, the manufacturer of the product can include the warning statement on the outer carton or on a hang tag attached to the product package.

To clarify how to determine the principal display panels, FDA is defining "principal display panels" of a product package as the panels of a package that are most likely to be displayed, presented, shown or examined by the consumer. In addition, the principal display panels should be large enough to accommodate all mandatory label information in a clear and conspicuous manner. The principal display panels may be on an outer carton for small vials holding e-liquids.

7. Waterpipe Tobacco

(Comment 253) One comment argued that the required warning should not be applied to hookah (or waterpipe tobacco) because there is a lack of substantial scientific evidence of the addictiveness of this product. The comment expressed the belief that the majority of waterpipe tobacco smokers in the United States use the product once a week or less. Another comment asserted that studies of noncigarette products, including waterpipe tobacco, show that these products are perceived to present less risk of harm and addictiveness, thereby encouraging use among young adults. The comment added that strong warnings regarding the addictiveness of all tobacco products may reduce trial and use in vulnerable populations (Ref. 259).

(Response) FDA disagrees that the addictiveness warning should not be applied to waterpipe tobacco. Waterpipe tobacco contains nicotine, which is the primary addictive chemical in tobacco products. Researchers have observed nicotine dependence characteristics in some users (Refs. 238, 239, 240), with one study showing that waterpipe tobacco use suppressed withdrawal symptoms just as cigarette smoking suppresses withdrawal symptoms (Ref. 240). Because waterpipe smoking sessions last longer than smoking a cigarette and there is increased smoke volume, a single session of waterpipe smoking (which typically lasts 20 to 80 minutes) likely exposes users to more nicotine than smoking a cigarette (which typically takes 5 to 7 minutes). Indeed, a meta-analysis of studies regarding waterpipe use showed that a single episode of waterpipe use is associated with exposure to 1.7 times the nicotine in a single cigarette.

FDA agrees that there is consumer confusion about the addictiveness of waterpipe tobacco. Whereas studies have shown that cigarette and waterpipe tobacco smoking deliver similar nicotine levels, one study showed that 46.3 percent of high school students wrongly believed that waterpipe tobacco is less addictive or less harmful than cigarettes, and one-third of these students wrongly believed that the product had less nicotine, no nicotine, or was generally less addictive than cigarettes (Ref. 260). Mistaken beliefs that waterpipe tobacco smoking is "safer or less addictive than cigarettes" were more prevalent among those who had ever used waterpipe tobacco (78.2 percent) compared to nonusers (31.6 percent) (Ref. 260). A study of nearly 2,000 university students found that waterpipe tobacco was considered by those students to be less addictive than e-cigarettes, marijuana, cigar products, smokeless tobacco, and cigarettes (Ref. 261). Research found that college students who had used waterpipes within the past 30 days considered them less addictive and less harmful than never-users did (Ref. 26). Similarly, another study found that "[freshmen college] students who used waterpipes and cigars perceived them as less harmful than regular cigarettes" (Ref. 262). Moreover, research has shown that such false beliefs about product risks can be a significant predictor of subsequent use behavior (Refs. 263, 264). For instance, adolescents with the lowest perceptions of short-term risks related to smoking were 2.68 times more likely to initiate smoking (Ref. 264). We note that the Surgeon General's 2014 Report provides an objective discussion of nicotine and addiction, where "nicotine addiction develops as a neurobiologic adaptation to chronic nicotine exposure. However, all forms of nicotine delivery do not pose an equal risk in establishing or maintaining nicotine addiction" (Ref. 9 at 112). Thus, pattern of use is a factor in the facilitation of addiction.

(Comment 254) One comment stated that FDA should require the addictiveness warning on all components of waterpipe tobacco use, including those products without nicotine or tobacco.

(Response) FDA disagrees. FDA finds that requiring health warnings on covered tobacco products only (and not on the components and parts that are not made or derived from tobacco) is appropriate to protect the public health, because youth and young adults will not be able to use such components and parts, and potentially suffer the consequences of tobacco use, *without also* using the covered tobacco product. In the event that FDA later determines it is appropriate for the protection of the public health to extend the warning requirements to components and parts that are not made or derived from tobacco, the Agency will initiate a new rulemaking in accordance with APA requirements.

8. Dissolvable Products

(Comment 255) One comment suggested that FDA recognize all dissolvable tobacco products as smokeless tobacco products for the purpose of warning label regulation and, as a result, subject all dissolvables to the smokeless warning requirements in section 204 of the Tobacco Control Act.

(Response) "Smokeless tobacco product" is defined in section 900(18) of the FD&C Act and for purposes of the warning requirements in CSTHEA (as amended by the Tobacco Control Act) as "any tobacco product that consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral or nasal cavity." Some dissolvable tobacco products do not meet the definition of "smokeless tobacco product" because they do not contain cut, ground, powdered, or leaf tobacco; instead, these products contain nicotine extracted from tobacco. These products are the dissolvable products covered by this final rule. Because they do not meet the statutory definition of a smokeless tobacco product, FDA cannot recognize them as such, as suggested by the comments. If FDA determines that the warning statements for any type of dissolvable product should be revised, or if any additional warning statements should be added to them, the Agency will initiate a new rulemaking in accordance with APA requirements.

(Comment 256) One comment stated that the use of an addictiveness warning would serve to protect the public health by more clearly identifying dissolvable products as addictive tobacco products and differentiating them from candy.

(Response) FDA agrees. Certain tobacco products have a candy-like appearance, frequently are sold next to candy, and are packaged in a way that makes them more attractive to children, which can mislead consumers to think that they are, in fact, candy (Refs. 54, 215). The addictiveness warning will clearly identify these products as tobacco products and help differentiate them from candy.

9. Premium Cigars and Unpackaged Cigars

(Comment 257) Several comments stated that not requiring warnings on premium cigars and those sold individually and without product packages would greatly diminish the effectiveness of the cigar warnings. One comment stated there are many instances where cigars are purchased as gifts and, in those instances, the recipients would not see these warnings. One comment also stated that if a purchaser receives with the premium cigar any wrapper, container, pack or bag, then FDA should require that it include a health warning. This would ensure that if the premium cigar is given for a celebratory occasion, or if a minor obtained a premium cigar from an adult and did not see the point-of-sale warning, the user would be warned of the health risks. Another comment stated that the warning labels should be permanently affixed to or inside the cellophane wrappers in which the cigars are sold and in a way that is clearly visible to potential purchasers.

(Response) FDA understands these concerns. However, for those cigars sold individually and not in a product package, the placement of warnings at the point of sale will be adequate to disseminate the required health information and is appropriate for the protection of the public health. For cigars that are sold in cellophane wrappers, these wrappers are considered packaging and, under this final rule, must include the required cigar warnings. In addition, FDA notes that youth attempting to purchase these cigars would be prohibited from doing so under the minimum age requirements included in this final rule.

(Comment 258) One comment expressed concern that the NPRM did not provide for warnings where premium cigars and cigars sold individually and without product packaging are sold online. The comment suggested that these cigars should either not be allowed to be sold individually or that individual cigars should be required to be packaged and include a warning label.

(Response) Under the Internal Revenue Code and TTB regulations, cigars that are taxpaid upon removal from the factory or release from customs custody must be in the packages in which they will be delivered to the ultimate consumer (bearing any marks or notices required by the Internal Revenue Code and TTB regulations) at the time of removal, and must remain in those consumer packages until taken from the package by the consumer or in the presence of the consumer. Removing taxpaid cigars from the package, other than in the presence of the waiting consumer, is a violation of the Internal Revenue Code. Cigars may nonetheless be sold individually, provided that the individual product packaging meets the requirements of the IRC and TTB regulations. An online retailer sending such individual cigars purchased online can comply with FDA's requirements by placing the warning statement on the box or container that is used to ship the product. In addition, FDA clarifies that the warning requirements apply to all forms of advertising, regardless of the medium in which they appear. As stated previously, advertisements subject to this final rule may appear in or on, for example, promotional materials (point-of-sale and non-point-of-sale), billboards, posters, placards, published journals, newspapers, magazines, other periodicals, catalogues, leaflets, brochures, direct mail, shelf-talkers, display racks, Internet Web pages, television, electronic mail correspondence, or be communicated via mobile telephone, smartphone, microblog, social media Web site, or other communication tool; Web sites, applications, or other programs that allow for the sharing of audio, video, or photography files; video and audio promotions; and items subject to the sale or distribution restriction in § 1140.34. As stated in § 1143.5(b)(2), the formatting requirements only apply to advertisements with a visual component. FDA intends to provide guidance on how to comply with the health warning requirements on unique types of media.

(Comment 259) One comment stated that premium cigars sold individually should include a health warning on the cigar tube, if applicable, or FDA should require retailers to provide a paper warning to the purchaser or put cigars in bags that are pre-printed with the warning labels.

(Response) It is unclear exactly how this comment intends to affix the warning to the premium cigar. If this comment is referring to affixing a warning to the cigar tube, this may damage the cigar and, therefore, is impractical. If this comment is seeking to add the warning to the tube that packages some individual cigars, FDA does not believe this is appropriate. Cigars sold individually in product packages, including cigars sold in tubes, must comply with the warning statement requirements for packaging. For cigars sold individually and not in product packages, the required warning statements must instead be posted at the retailer's point of sale. FDA believes that the point of sale signage requirement will ensure that premium cigar purchasers, as well as purchasers of other individual cigars, receive the required health warnings while allowing persons selling or distributing the cigars to maintain existing business practices.

(Comment 260) One comment expressed concern about retailers having to forfeit counter space for the placement of health warnings for cigars sold individually and not in product packages. The comment stated that this space is reserved for some of the most profitable items for sale in convenience stores. The comment also stated that the U.S. Circuit Court of Appeals for the District of Columbia struck down a similar, judicially imposed warning requirement that required retailers to set aside valuable retail space to display a point-of-sale sign. (*United States* v. *Philip Morris USA Inc.*, 566 F.3d 1095 (D.C. Cir. 2009).)

(Response) FDA believes that the point-of-sale warnings are necessary and appropriate for the protection of public health. FDA notes that the requirement only applies where cigars are sold individually and unpackaged, and will ensure that consumers of these products are exposed to the same health warnings as consumers of other cigar products. FDA also believes the point-of-sale warnings are necessary to prevent manufacturers and retailers of cigars from circumventing the warning requirement by selling their products without packaging.

Moreover, the *United States* v. *Philip Morris* holding cited in the comment was not on the merits and in any event is not applicable here. That case involved corrective statements mandated in a civil Racketeer Influenced and Corrupt Organizations Act (RICO) case brought against the United States' major cigarette companies. After finding the defendants liable for racketeering and fraud, the lower court issued an injunction that required the defendants to disseminate public statements in order to prevent and restrain future fraud. The statements were required to appear in various types of media—including large-point-of-sale signs present at the checkout counter of retailers that participated in defendants' "participating retailer" programs. On appeal, noting that the retailers were not involved in the RICO litigation but were negatively affected by the injunctive remedy, and had not had the opportunity to present arguments against the point-of-sale location before the lower court ruled, the appellate court vacated the point-of-sale requirement on due process grounds, and remanded for further consideration by the lower court. *Philip Morris USA Inc.*, 566 F.3d at 1141–42. The appellate court did not rule on whether mandatory point-of-sale corrective statements in valuable retail space are permissible under the RICO statute, but simply ruled that before the district court could impose such a requirement, the RICO statute required "considering the rights of third parties and existing contracts" (id. at 1145). By contrast, these warning requirements are being issued under the Tobacco Control Act, not the RICO statute; and are the product of notice-and-comment rulemaking.

10. Cigarettes and Roll-Your-Own

(Comment 261) Some comments stated that FDA should conform the proposed health warnings for cigarette tobacco and roll-your-own tobacco to the federally mandated health warnings for cigarettes required by section 4(s) of FCLAA and to health warnings that FDA mandates for cigarettes in the future.

(Response) FDA disagrees. Cigarette tobacco and roll-your-own tobacco do not meet the definition of the term "cigarette" in section 3(1) of FCLAA. Because cigarette tobacco and roll-your-own tobacco are not cigarettes as defined by FCLAA, they do not need to comply with section 4 of FCLAA requiring cigarette warnings and, therefore, do not contain any warning to alert consumers of the health effects of these products. Instead, the Tobacco Control Act defines cigarette tobacco and roll-your-own tobacco in sections 900(4) and 900(15) of the FD&C Act, respectively. The lack of a warning on these tobacco products may lead consumers to believe that they are safe products. Therefore, with this final rule, FDA is requiring that manufacturers of such products comply with the addiction warning in § 1143.3 and any other future health warnings that FDA mandates for these products, where appropriate.

(Comment 262) Some comments expressed concern about the following warning as applied to pipe tobacco products: "WARNING: This product contains nicotine derived from tobacco. Nicotine is an addictive chemical." They stated that this warning is not appropriate for these products because the first sentence of the warning suggests that it is targeted at e-cigarettes whose nicotine is derived from tobacco, not tobacco itself. Other comments expressed concern that the word "derived" would not be well understood by the majority of consumers and introduced unnecessary complexity. They also noted that the statement that the nicotine is derived from tobacco does not provide information that is relevant to the user's health. One comment suggested a number of changes to the proposed addiction warning, including a simpler alternative: "WARNING: This product contains nicotine. Nicotine is an addictive chemical."

(Response) FDA agrees with concerns using the word "derived." FDA has concluded that the suggested warning statement "WARNING: This product contains nicotine. Nicotine is an addictive chemical" is a more appropriate warning label because it provides an accurate warning for both products that contain leaf tobacco and products that contain nicotine derived from tobacco. It is also clearer and does not introduce unnecessarily complex terms that may make it more difficult for consumers to understand and appreciate the risks of addiction. Similarly, FDA is revising the alternative statement to read "This product is made from tobacco." to remove use of the word "derived," which may not be easily understood. However, FDA disagrees with comments stating that this warning should not be required on pipe tobacco packages because pipe tobacco contains nicotine, which is the primary addictive constituent in tobacco products.

Thus, FDA has changed § 1143.3(a)(1) to require that for cigarette tobacco, roll-your-own tobacco, and covered tobacco products other than cigars, it is unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States such product unless the tobacco product bears the following required warning statement on each product package label: "WARNING: This product contains nicotine. Nicotine is an addictive chemical."

11. Addictiveness Warning

(Comment 263) One comment stated that the need to inform consumers about the addictiveness of nicotine has been implicitly recognized by a number of manufacturers of e-cigarette products. The comment stated that a recent investigation by the staff of 11 U.S. Senators and Representatives of the practices of 9 of the largest e-cigarette manufacturers revealed that, although their product warning labels "lack uniformity and may confuse consumers," 6 of the 9 companies included some form of nicotine warning as part of their packaging or instructions for use, in addition to the nicotine warning these companies included to satisfy California's Proposition 65 (see Ref. 31). Although the warnings are not as comprehensive as FDA's required health warnings in terms of size and prominence, they reflect the companies' own recognition that their products are addictive and that consumers should be informed of their addictive properties.

(Response) Requiring health warnings on all newly deemed tobacco products will help consumers better understand and appreciate the addictive properties of these products.

(Comment 264) Some comments questioned whether large cigars, particularly premium cigars, should be required to carry an addiction warning because users do not inhale the cigar smoke.

(Response) Regardless of whether cigar smokers inhale, they are still subject to the addictive effects through nicotine absorption (Refs. 32, 34). Cigar smoke dissolves in saliva, allowing the smoker to absorb sufficient nicotine to create dependence, even if the smoke is not inhaled (Refs. 34, 35). Therefore, consumers using premium or other cigars can become addicted to cigars given the absorption of nicotine. Accordingly, FDA finds that it is appropriate for the protection of the public health to require this warning on all cigars.

12. Alternative Statement/Certification for Products Without Nicotine: "This Product Is Derived From Tobacco."

(Comment 265) Several comments expressed concern about requiring a tobacco product that does not contain nicotine to have an alternate health warning stating that, "this product is derived from tobacco." These comments stated that future products that are not derived from tobacco would fall outside of FDA's jurisdiction and, therefore, would not be required to include this statement on product packages.

(Response) FDA agrees. If a product is not made or derived from tobacco, it would not be required to bear the alternative statement. However, if a product is made or derived from tobacco but does not contain nicotine, the product is required to bear the alternative statement. As discussed in section XVI.B, FDA is revising this alternative statement to read "This product is made from tobacco."

(Comment 266) Several comments stated that FDA should not permit use of the alternate statement "This product is derived from tobacco" because there are studies showing instances of e-cigarette products being labeled as zero nicotine and actually containing nicotine (Refs. 20, 170).

(Response) FDA disagrees. If a tobacco product manufacturer has mislabeled its product to indicate that it does not contain nicotine when in fact it actually does, the manufacturer will be subject to enforcement action for misbranding and the product will be required to bear the addictiveness warning (instead of the alternative statement).

(Comment 267) A few comments suggested that the alternative warning statement will cause consumer confusion because most people believe nicotine causes cancer and the alternative statement suggests there is a difference in the health risks based on solely the presence of nicotine. Other comments stated that the alternative statement should not use the term "tobacco product" because e-cigarettes do not contain tobacco leaf. These comments also stated that the words "tobacco product" could also potentially cause confusion because consumers do not consider e-cigarettes to be tobacco products.

(Response) FDA disagrees that the language in the alternative statement will cause confusion. The alternative statement does not use the term "tobacco product" and does not state that any ENDS product contains tobacco. Instead, the alternative statement included with this final rule states: "This product is made from tobacco."

FDA is not aware of any currently marketed tobacco product that does not contain nicotine. If such a product is introduced in the future, FDA believes it is important that both consumers and retailers be alerted that, although it may not contain nicotine, it is nevertheless a tobacco product. From a public health perspective, FDA believes that it is important to convey this factual information to consumers because tobacco products (*i.e.*, products made or derived from tobacco) could contain other addictive chemicals (like anabasine or nornicotine) and/or dangerous toxicants and can be psychologically addictive as well. For example, users of de-nicotinized cigarettes consistently report a significant degree of subjective satisfaction (Refs. 265, 266, 267). The alternative warning statement is especially important in light of the recent proliferation of novel tobacco products (*e.g.*, dissolvables that may appear like candy) that do not resemble traditional tobacco products, and therefore, which consumers may not know are made from tobacco. As the comments noted, some consumers are not even aware that e-cigarettes are tobacco products.

FDA believes that the fact that a product without nicotine is made from tobacco is important factual information that should be conveyed to both consumers and retailers. In addition to providing consumers with significant information that could affect their health, the statement will help ensure that retailers are aware that the product is and must be treated as a tobacco product. This will result in increased retailer compliance with the minimum age and photo identification requirements, as well as other applicable requirements. FDA believes that this factual alternative statement is the simplest, least burdensome, and yet effective way to inform both consumers and retailers that, despite the absence of nicotine, the product is still a tobacco product that, like other tobacco products, may not be purchased by or sold to persons under the age of 18 and requires the presentation and examination of a photo identification card.

13. Warning: Cigars Are Not a Safe Alternative to Cigarettes

(Comment 268) A few comments noted that evidence indicates there is a widespread perception, particularly among young people, that cigars are less hazardous than cigarettes and this perception may be contributing to the increased incidence of cigar smoking. According to the comments, one study found that adult cigar smokers in general are three times more likely to believe cigars are a safe alternative to cigarettes compared to those who do not smoke cigars (Ref. 268). They also cited an online survey of college students at six colleges in the southeastern United States, which found that smokers of little cigars and cigarillos "were more likely to report perceiving the harm of little cigars, cigarillos, and cigars to be less than that of cigarettes" when compared to nonusers (Ref. 269). In addition, a study of middle school and high school students in Massachusetts found that 34.9 percent of current youth cigar users agreed that "cigars are not as bad for you as cigarettes," while only 12.2 percent of the total study population of students agreed with the statement (Ref. 270). The comments also cited a similar study that included a focus group study of 230 middle school, high school, and college students, which found that 30 percent of teen cigar users made the statement that, compared to cigarettes, cigars are less risky, and only 10 percent of teens with no cigar experience made that statement (Ref. 271).

(Response) FDA agrees that there is an unsubstantiated perception, especially among young people, that cigars are less hazardous than cigarettes (*see* 79 FR at 23158). This warning requirement will help to consumers understand and appreciate the risks of cigars.

14. Warning: Tobacco Smoke Increases the Risk of Lung Cancer and Heart Disease, Even in Nonsmokers

(Comment 269) The comments differed as to whether the warning "Tobacco Smoke Increases the Risk of Lung Cancer and Heart Disease, Even in Nonsmokers" was appropriate. Some comments thought that the health warning was appropriate. At least one noted that a causal relationship exists between secondhand smoke exposure and lung cancer among lifetime nonsmokers, and individuals living with smokers had a 20 to 30 percent increase in the risk of developing lung cancer from secondhand exposure (Ref. 272 at 445). They stated that, since all cigars produce higher levels of toxicants than cigarette smoke, the science clearly supports the proposed warning.

However, several other comments stated that the scientific evidence does not support the claim that "secondhand smoke causes premature death and disease in youth and in adults who do not smoke." One of these comments stated that the epidemiological links between "being married to a smoker" and increased disease are tenuous at best. While these comments agreed that on a per-stick basis, cigars can produce larger amounts of environmental tobacco smoke than do cigarettes, they stated that it is not accurate to conclude that this exposes household members to a considerable involuntary health risk.

(Response) FDA agrees with the comments stating that this warning is appropriate for the protection of the public health. It is well established that secondhand smoke causes premature death and disease in youth and in adults who do not smoke (Ref. 272 at 445, 532). Adult exposure to secondhand smoke has immediate adverse effects on the cardiovascular system and causes lung cancer and coronary heart disease (id.). Tobacco smoke contains over 7,000 compounds, and there are more than 70 carcinogens in sidestream and mainstream smoke generated from cigars (Refs. 9, 70, 273). Mainstream cigar smoke is the smoke that one draws into his or her mouth from the butt end or mouthpiece of a cigar; whereas sidestream cigar smoke is the smoke emitted from the burning cone of a cigar during the interval between puffs (Ref. 69 at 65). Cigar smoke "tar" appears to be at least as carcinogenic as cigarette smoke "tar" (Ref. 272). The Surgeon General recently reiterated that cigar smoke contains the same toxic substances as cigarette smoke, with varying concentrations of these constituents found in different types and sizes of cigars (Ref. 69 at 17–18; Ref. 272 at 362).

There is a causal relationship between lung cancer and secondhand smoke. Exposure of nonsmokers to secondhand smoke also has been shown to cause a significant increase in urinary levels of metabolites of tobacco-specific nitrosamines, a carcinogen that specifically links exposure to secondhand smoke with an increased risk for lung cancer (Ref. 69 at 65). All cigars produce higher levels of carcinogenic tobacco-specific nitrosamines per gram in mainstream cigar smoke than cigarettes produce in mainstream cigarette smoke (id. at 75–76). Cigar smoke also produces measurable amounts of lead and cadmium (id. at 75–76). Little cigars with filter tips and regular cigars contain higher levels of certain nitrosamines in sidestream smoke than do filtered tip cigarettes (Ref. 69 at 81).

The Surgeon General has reiterated that there is considerable evidence that certain nitrosamines are major factors in the development of lung cancer (Ref. 272 at 30). According to the Surgeon General, the evidence is sufficient to infer a causal relationship between secondhand smoke exposure and lung cancer among lifetime nonsmokers (Ref. 272 at 434). Individuals living with smokers have a 20 to 30 percent increase in risk of developing lung cancer from secondhand exposure (id. at 445). Although data particular to cigars are not available, FDA believes it is reasonable to expect that cigar smoke would produce similar effects as cigarette smoke, given that data from the National Cancer Institute (NCI) cigar monograph shows that some carcinogens determined to cause lung cancer are present at higher levels in cigar smoke than in cigarette smoke and are present at levels comparable to other carcinogens linked to lung cancer (Ref. 69 at 76–93).

There is also a causal relationship between secondhand smoke and heart disease. The health warning statement indicating that tobacco smoke can cause heart disease is thoroughly supported by the evidence reiterated in reports from the Surgeon General. FDA believes it is reasonable to conclude that this finding would produce similar effects with respect to secondhand cigar smoke exposure based on the similar smoke profiles for cigars and cigarettes, the risk of coronary heart disease associated with active cigar smoking, and the low levels of toxicant exposure that can cause coronary heart disease (Ref. 272).

In a 2006 Surgeon General's report regarding the health effects of exposure to secondhand smoke, the evidence demonstrated that exposure of adults to secondhand smoke had immediate adverse effects on the cardiovascular system and caused coronary heart disease (id. at 11). Secondhand smoke increased the risk of coronary heart disease nearly as much as active heavy smoking. In fact, the estimated increase in risk of coronary heart disease from exposure to secondhand smoke was 25 to 30 percent above that of unexposed persons (id. at 519; Ref. 273 at 532). Based on these data, the Surgeon General concluded that "the evidence is sufficient to infer a causal relationship between exposure to secondhand smoke and increased risks of coronary heart disease morbidity and mortality among both men and women" (Ref. 272 at 15). The IOM agreed, concluding that there is a causal relationship between secondhand smoke exposure and cardiovascular disease, as well as a causal relationship between secondhand smoke exposure and acute myocardial infarction (Ref. 275 at 219).

Even a relatively brief exposure to secondhand tobacco smoke can lead to heart disease, as some studies have demonstrated. The IOM found there is compelling circumstantial evidence that a relatively brief exposure to secondhand smoke can bring about an acute coronary event (id. at 220).

Given that the effects of secondhand smoke on coronary heart disease are linked to the combustion of tobacco itself, FDA concludes that exposure to secondhand cigar smoke can cause the same or similarly dangerous effects as exposure to secondhand cigarette smoke. Thus, FDA believes the warning statement that "Tobacco smoke increases the risk of lung cancer and heart disease, even in nonsmokers" is appropriate for the protection of the public health.

15. Warning: Cigar Smoking Can Cause Cancers of the Mouth and Throat, Even if You Do Not Inhale

(Comment 270) Several comments disagreed with FDA's rationale for the warning "Cigar smoking can cause cancers of the mouth and throat, even if you do not inhale." These comments noted that the rationale depends almost exclusively on Monograph 9 from the National Cancer Institute, which did not distinguish among cigar types and, therefore, should not be required for premium cigars. They also stated that cigars are safe products if users do not inhale the smoke, as illustrated by experimental data showing minimal toxicity because cigar smokers do not inhale (Refs. 32, 74).

(Response) FDA disagrees. The fact that Monograph 9 did not distinguish among types of cigars does not mean that it only applies to certain cigar types. In fact, the statement in the Monograph applied to all types of cigars. Any cigar use exposes the mouth and throat to tobacco smoke and can cause several different types of cancer even without inhalation (Refs. 69, 104). For example, one study found an increased risk of head and neck cancers for those who do not smoke cigarettes but had previously smoked cigars (Ref. 104).

While inhaling cigar smoke poses higher risk rates than not inhaling, significant risk still exists for those who do not inhale. In addition, most cigar smokers do inhale some amount of smoke and are not aware that they are doing it, including those who do not intend to inhale (Ref. 33).

16. Reproductive Health Warning for Cigars

In the proposed deeming rule, FDA proposed to require four of the five warnings already included on most cigar packages and in most cigar advertisements as a result of settlement agreements between the FTC and the seven largest U.S. cigar manufacturers. (See, *e.g., In re Swisher International, Inc.,* Docket No. C–3964.) FDA proposed not to require the fifth warning (SURGEON GENERAL WARNING: Tobacco Use Increases the Risk of Infertility, Stillbirth and Low Birth Weight) because although cigarette smoke causes these health effects (and cigar smoke is similar to cigarette smoke), the Agency stated it was not aware of studies specifically linking cigars to all three reproductive effects. FDA requested comment on its proposal to require the use of only four of the five current FTC warnings for cigars.

During the comment period, FDA received several comments encouraging FDA to reconsider its proposal and finalize the rule to include all five warnings. In response to these comments, FDA reconsidered whether to require use of the FTC reproductive health warning. While FDA agrees that FTC's general warning statement "Tobacco Use Increases the Risk of Infertility, Stillbirth and Low Birth Weight" is a factually correct statement and recognizes that cigar smoke is similar to cigarette smoke in both chemical content and effects, on balance, FDA prefers a warning that is specific to cigars. Therefore, FDA has reconsidered the issue and is including a fifth warning statement to read "WARNING: Cigar Use While Pregnant Can Harm You and Your Baby." which is well supported by direct evidence and is appropriate for the protection of the public health. However, FDA is also allowing manufacturers to use the FTC warning, which is appropriate for the protection of the public health, as an optional alternative to the new reproductive health warning.

The FTC warning is about tobacco smoke generally, and the statement itself is well supported by scientific evidence. Researchers have confirmed that smoking causes negative effects on fertility, pregnancies, and infants and children born to women who smoke. For example, cigarette smoking increases rates of preterm delivery, shortened gestation, and orofacial clefts, and studies have indicated that women who smoke are twice as likely to have low birth weight infants as women who do not smoke (Ref. 9 at p. 499; Ref. 275 at pp. 569, 576). In addition, scientific evidence supports that women who smoke have an increased risk of infertility and stillbirth (Ref. 276). It also causes an increased risk of sudden infant death syndrome (SIDS) for infants whose mothers smoke during and after pregnancy (Ref. 275 at pp. 587 and 601). In addition, scientific evidence supports the conclusion that cigar smoke has similarly toxic effects. NCI's Monograph 9 states:

> there is no reason to expect that cigar smoke would be any less toxic for the mother or fetus. Regular cigar smoking, particularly with inhalation, should be presumed to have risks similar to that of cigarette smoking for the pregnant smoker.

(Ref. 69 at 10). On balance, FDA prefers a warning that is specific to cigars, so FDA is finalizing this rule with different warning language specifically relating to cigars that the Agency concludes is appropriate for the protection of the public health. However, given the accuracy of the original FTC warning on its face, given that cigar smoke contains and delivers the same harmful constituents as cigarette smoke, and given extensive evidence that cigar smoke has similar physiological effects on the body, it is also appropriate for the protection of the public health for FDA to allow the use of the optional alternative (SURGEON GENERAL WARNING: Tobacco Use Increases the Risk of Infertility, Stillbirth and Low Birth Weight) to the reproductive health warning.

FDA selected the new warning language for several reasons. First, FDA finds that this warning is supported by direct scientific evidence that nicotine adversely affects maternal and fetal health (Ref. 9). Second, this warning uses the term "cigar use" rather than "tobacco use," because the warning would appear on cigars only. Third, FDA finds that this is powerful and comprehensible phrasing, which will be understandable to a wide audience. Nevertheless, FDA recognizes that many cigar manufacturers currently use FTC's truthful warning on the reproductive risks of tobacco smoke. Therefore, FDA is also allowing an optional alternative (SURGEON GENERAL WARNING: Tobacco Use Increases the Risk of Infertility, Stillbirth and Low Birth Weight) to the reproductive health warning to comply with the warning requirements for cigars. FDA expects that allowing the optional alternative will benefit entities bound by the FTC consent decrees.

(Comment 271) Comments from cigar makers contended that because the NPRM and the FTC consent orders both required five warnings, but not the same five warnings, manufacturers would not be able to use one set of warnings to comply with both regimes. As one comment put it, "For example, manufacturers could not ensure a random display of FDA's five warnings 'in as equal a number of times as is possible,' as required by the NPRM, while including the reproductive effects warning required by FTC in that random distribution." This comment went on to state that a reproductive warning for cigars is also required by California's Proposition 65, and added that in response to an inquiry from FTC at the time of the FTC consent orders, the California Attorney General agreed that "compliance with the FTC Consent Order will result in compliance with Proposition 65." (Comments of Altria Client Services Inc. on behalf of John Middleton Co., FDA–2014–N–0189–79814.)

Other comments urged that there is scientific support to require a reproductive warning for cigars. For example, one comment asserted that this warning is based on data related to cigarette smoke, and given that cigarette smoke is very similar to cigar smoke, and in many cases, cigar smoke is more dangerous than cigarette smoke, it is a logical conclusion that this warning is appropriate for cigars. Another comment noted that the 2014 U.S. Surgeon General Report on tobacco use devotes an entire chapter to the health effects of nicotine and documents that nicotine crosses the placenta and concentrates in the fetus (Ref. 9). The comment also noted that nicotine constricts vessels and thus limits the amount of nutrients and oxygen delivered to the fetus.

(Response) While FDA is unaware of data directly and explicitly linking cigar smoke to such reproductive issues, FDA recognizes the similarities between cigarette smoke and cigar smoke. On balance, FDA prefers a warning specific to cigars. However, as noted previously, FDA is allowing an optional alternative (SURGEON GENERAL WARNING: Tobacco Use Increases the Risk of Infertility, Stillbirth and Low Birth Weight) to the reproductive health warning to comply with the warning requirements for cigars. FDA expects that allowing the optional alternative will benefit entities bound by the FTC consent decrees.

(Comment 272) One comment expressed concern that the exclusion of the reproductive effects warning in a final rule (*i.e.*, the FTC warning that states "Tobacco Use Increases The Risk Of Infertility, Stillbirth And Low Birth Weight"), and the subsequent advertising and sale of cigar packages without the warning, could result in claims that the FTC consent orders have been violated. The comment requested that FDA ensure that the absence of such warning in any final rule will not result in a claim that the FTC consent orders have been violated.

(Response) In the NPRM, FDA indicated that it planned to consult with FTC "to harmonize national requirements for health warnings on cigar product packages and in advertisements" (79 FR 23142 at 23163). As noted previously, FDA has given careful consideration to the comments and the scientific evidence on this issue and has decided to require a reproductive health warning for cigars, and the Agency has discussed this evidence and decision with FTC. At this time, FDA is not aware of any concerns from FTC regarding the cigar warnings included with this final rule.

17. Rotation of Warnings on Advertisements

(Comment 273) Several comments stated that rotational warning requirements should be simple, streamlined, and easily administrated, especially for small businesses. One comment suggested that it should be sufficient to print equal numbers of labels containing all six warnings and rely on the randomness of market distribution patterns without the administrative burden of demonstrating to FDA in a written rotational plan, and in subsequent facility inspections, that FDA can determine that each different warning was equally displayed to each consumer for each brand during a 12-month period.

(Response) While FDA recognizes that the random display and distribution of warning statements on cigar product packages and the rotation of statements on advertisements can result in administrative and financial costs for cigar manufacturers, FDA does not believe it would be sufficient to rely on the randomness of market distribution patterns. Relying on random distribution would not ensure that the different health warning messages are reaching as many individuals as possible, and the health warnings may grow stale from overuse if repeated too many times for the same individual. Thus, FDA is requiring warning statements for cigar packages to be randomly displayed in each 12-month period in as equal a number of times as possible on each brand of cigar. The required warning statements also are required to be randomly distributed in all areas of the United States in which the product is marketed. The random display and distribution of required warning statements for cigar packages must be carried out in accordance with a warning plan submitted by the cigar manufacturer, importer, distributor, or retailer to, and approved by FDA.

FDA is also requiring that the required warning statements be rotated quarterly in alternating sequence in each advertisement for each brand of cigar, regardless of whether the cigar is sold in product packaging. This rotation of warning statements in cigar advertisements also must be done in accordance with a warning plan submitted to FDA by the cigar manufacturer, importer, distributor, or retailer to, and approved by FDA. As stated in § 1143.5(c)(3) of this final rule, each person required to randomly display and distribute or rotate warnings in accordance with an FDA-approved plan under this part must submit a proposed warning plan to FDA no later than either 12 months after [date of publication of final rule], or 12 months before advertising or commercially marketing a product that is subject to such requirement, whichever is later. This 12-month submission timeframe provides cigar entities time to develop and submit warning plans to FDA. FDA encourages firms to submit warning plans any time within this 12-month period, and FDA plans to begin reviewing warning plans as soon as they are received. FDA is establishing this effective date at 12 months before the effective date of the required warnings for cigars described under part 1143 (24 months after the publication of the final rule) because the Agency anticipates that there will be a need for communication with submitters during its review of the warning plan submissions. This submission effective date also helps FDA to ensure that its surveillance program for compliance with the warning label requirements under § 1143 is implemented as of the effective date of 24 months after the publication of the final rule.

FDA intends to work with manufacturers, importers, distributors, or retailers to get an approved warning plan in place. Cigar entities may wish to contact FDA to discuss the submission of their warning plans in order to make the approval process more orderly and efficient. FDA's review and approval of a warning plan enables the Agency to more effectively conduct surveillance and inspection activities to ensure compliance with the warning label requirements under § 1143, once effective, by providing a guide regarding the expected rotation of the various warnings as required by the regulation. In addition, the review and approval process will help manufacturers, importers, distributors, and retailers understand the requirements under this part; and help cigar entities minimize potential economic loss from the commercial distribution of nonconforming products in the market.

Additionally, FDA believes that it will be able to complete its review of the submitted warning plans by the effective date of the required cigar warnings. In FDA's experience with the review of warning plans for smokeless tobacco products, no smokeless tobacco product manufacturer, importer, distributor, or retailer was delayed or prevented from advertising or distributing smokeless tobacco products due to FDA's review of its warning plan, and FDA does not anticipate a different outcome here. FDA intends to issue a guidance document within 12 months after publication of the final rule to assist the cigar industry with the requirements for the submission of warning plans. In addition, if FDA receives a higher volume of warning plans than anticipated, and determines that it will not be able to review and approve submitted warning plans by the 24-month effective date, FDA may also consider implementing a compliance policy to ensure that cigar entities are not delayed or prevented from advertising or distributing cigars due to FDA's review of their warning plans.

These requirements are consistent with those established by Congress in the Tobacco Control Act for currently regulated tobacco products. Section 3 of CSTHEA (as amended by section 204 of the Tobacco Control Act) requires the random distribution and rotation of warnings for smokeless tobacco products. Further, rotation of cigar warning statements already occurs under the FTC consent decrees. The WHO also has recognized the need to rotate health warnings for tobacco products. The WHO's FCTC, evidence of a strong worldwide consensus regarding a regulatory strategy for addressing the serious negative impacts of tobacco products, calls for warnings that are "rotating" and "large, clear, visible and legible" (WHO FCTC article 11.1(b)).

(Comment 274) One comment stated that the proposed requirement that the warning statements be permanent or irremovable is ambiguous and does not specifically address whether labels applied by manufacturers (which manufacturers intend not to be removed but technically are removable) are compliant with the rule.

(Response) Section 1143.9 requires that the health warnings be indelibly printed on or permanently affixed to packages and advertisements. If a warning statement can be removed, then it is not permanent and does not meet the requirements of § 1143.9. Removable or impermanent warnings on packages and in advertisements could become separated from the package or advertisement and thus would not meet the requirement that they be conspicuous on the package or advertisement. Removable warnings would run counter to FDA's purpose of effectively conveying risk information to consumers.

18. Warnings for E-Liquids

(Comment 275) Several comments recommended that FDA require multiple and rotating warnings on all e-liquids that contain nicotine. They stated the potential consequences of nicotine use need to be listed explicitly, as explicit warnings are associated with greater perception of potential danger than vague or general warnings (Ref. 277). Suggestions for e-cigarette warning label content included: (1) Toxicity and potential lethality of nicotine; (2) danger to skin and eyes; (3) danger from ingestion of nicotine liquids; (4) other potential health hazards, including burns and explosions, from ENDS use; (5) keep out of reach of children; (6) information about the heating mechanism (coil) and energy source (battery); (7) information about overheating or overuse, including risk of fire (if applicable); (8) warnings or precautions about use in or near water as well as any electrical shocks; and (9) warnings and instructions about replacing components and parts.

Another comment believed the Agency should consider requiring manufacturers of e-cigarettes to provide additional information for consumers in e-cigarette packaging, and as appropriate, for other newly deemed tobacco products. The comment suggested that this information could be presented using communication principles similar to those used in "Drug Facts" for over-the-counter drugs and should include information such as the nicotine addiction warning, age limits, warnings about danger to children and pets, and information about use during pregnancy and breast feeding.

(Response) At this time, FDA finds it is appropriate for the protection of the public health to require the warning regarding the addictiveness of nicotine on ENDS. However, as we have stated previously, this deeming regulation is a foundational rule, affording the Agency the ability to publish additional regulations as necessary and appropriate for the protection of the public health. FDA remains concerned about all of the health risks and hazards listed in this comment and will be focusing efforts and resources on future efforts to prevent nicotine poisoning in both users and nonusers. Therefore, FDA issued an ANPRM prior to this deeming rule, seeking comments, data, research, or other information that may inform regulatory actions FDA might take with respect to nicotine exposure warnings and the use of child-resistant packaging. In addition, elsewhere in this issue of the **Federal Register**, FDA has made available draft guidance for public comment, which when final will represent FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products, including recommendations for exposure warnings and child-resistant packaging that would help to support a showing that the marketing of a product is appropriate for the protection of public health.

(Comment 276) Several comments noted that FDA should establish alternative methods for providing health warnings on tobacco products with small packages, such as e-cigarettes. One comment noted that FDA has created special rules for small food packages and small over-the-counter drug packages where the size of the package prevents the manufacturer from satisfying certain mandatory labeling requirements. This comment suggested that FDA implement similar alternatives for displaying warnings on small e-cigarette packages, and that the warning on advertising materials should not exceed 10 percent of the area of the advertisement. Another comment asserted that many e-liquids are packaged in relatively small 10 milliliter vials and that FDA should consider package size and design when mandating health warnings.

(Response) To address the issue of tobacco products with small packages, we have added § 1143.3(d) to this final rule, which states that a tobacco product that would otherwise be required to bear the warning in § 1143.3(a)(1) but is too small or otherwise unable to accommodate a label with sufficient space to bear the information is exempt from compliance with the requirement *provided* the information and specifications required under § 1143.3(a)(1) and (a)(2) appear on the carton or other outer container or wrapper if the carton, outer container, or wrapper has sufficient space to bear such information, or appears on a tag otherwise permanently affixed to the tobacco product package. In these cases, the carton, outer container, wrapper, or tag will serve as the location of the principal display panels. For example, FDA is aware that e-liquids are frequently sold in small vials that may be unable to accommodate a label with sufficient space to bear a health warning. In addition, small boxes of replacement cartridges will be required to carry a warning if they contain nicotine or tobacco, or are otherwise made or derived from tobacco, and, therefore, are covered tobacco products. Such products also may not have sufficient space to bear a health warning. In these cases, a manufacturer could include such information on the carton or other outer container or wrapper if the carton, outer container, or wrapper has sufficient space to bear the information, or appear on a tag that is permanently affixed to the tobacco product package. With respect to the part of this comment stating that health warnings on advertising materials should not exceed 10 percent of the area of the advertisement, see the NPRM (79 FR 23142 at 23164) for additional discussion regarding the need for prominent health warnings.

XVII. National Environmental Policy Act

The Agency has carefully considered the potential environmental effects of deeming products to be subject to the FD&C Act and the age and identification restrictions. FDA has concluded that the actions will not have a significant impact on the human environment, and that an environmental impact statement is not required. The Agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

FDA's responses to comments regarding the proposed Environmental Assessment are included in the following paragraphs.

(Comment 277) One comment stated that FDA erroneously relied upon the environmental impact analyses required by the National Environmental Policy Act (NEPA), suggesting that the Agency should review and analyze the total environmental impact of the rule.

(Response) FDA disagrees. The analysis of a regulation's environmental impact is governed by NEPA, which requires FDA to assess, as an integral part of its decisionmaking process, the environmental impacts of any proposed Federal action to ascertain the environmental consequences of that action on the quality of the human environment and to ensure that the interested and affected public is appropriately informed. FDA satisfied these requirements with the preparation of a proposed environmental assessment and a final environmental assessment (Ref. 278).

(Comment 278) One comment requested that FDA issue a new Environmental Assessment due to "the loss of irreplaceable cultural historical resources that directly relate to the heritage of the [Ybor City National Historic Landmark] District, the City of Tampa, the State of Florida[, and] the United States of America."

(Response) FDA denies this request. FDA prepared its Environmental Assessment in accordance with the requirements of 21 CFR part 25. FDA properly accounted for all potential environmental consequences of that action on the quality of the human environment. Therefore, a new Environmental Assessment is unnecessary and contrary to the requirements of NEPA (Ref. 279).

XVIII. Analysis of Impacts

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. We believe that this final rule is a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. We find that the final rule will have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $144 million, using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. This final rule would result in a 1-year expenditure that meets or exceeds this amount.

This final rule finalizes Option 1 of the NPRM, which deems all products meeting the statutory definition of "tobacco product," except accessories of a newly deemed tobacco product, to be subject to chapter IX of the FD&C Act. This final rule also finalizes additional provisions that would apply to certain newly deemed products as well as to certain other tobacco products. Once deemed, tobacco products become subject to the FD&C Act and its implementing regulations. The FD&C Act requirements that will apply to newly deemed products include establishment registration and product listing, ingredient listing, submissions prior to the introduction of new products, and labeling requirements. Free samples of newly deemed tobacco products will also be prohibited. The additional provisions of this final rule include minimum age and identification requirements, vending machine restrictions, and required warning statements for packages and advertisements.

While FDA currently has authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco under chapter IX of the FD&C Act, under the final rule, all additional tobacco products that meet the statutory definition, except accessories of those newly deemed tobacco products, will be subject to chapter IX of the FD&C Act and its implementing regulations.[16] These products include cigars, pipe tobacco, waterpipe tobacco, ENDS (including e-cigarettes), and other novel tobacco products such as certain dissolvable products and gels. These products further include components and parts of the newly deemed products, including pipes, e-liquids, atomizers, batteries, cartomizers (atomizer plus replaceable fluid-filled cartridge), tank systems, flavors for e-liquids, vials that contain e-liquids, programmable software, flavor enhancers for waterpipe tobacco, waterpipe cooling attachments, water filtration base additives, flavored waterpipe tobacco charcoals, and waterpipe bowls, valves, hoses, and heads.

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[16] As stated in section 201(rr) of the Federal Food, Drug, and Cosmetic Act in relevant part, a tobacco product: (1) Means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product); and (2) Does not mean an article that is a drug under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)), a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)), or a combination product described in section 503(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)).

The final deeming action differs from most public health regulations in that it is an enabling regulation. In addition to directly applying the substantive requirements of chapter IX of the FD&C Act and its implementing regulations to newly deemed tobacco products, it enables FDA to issue further regulations related to such products that are appropriate for the protection of the public health. We expect that asserting our authority over these tobacco products will enable us to propose further regulatory action in the future as appropriate, and those actions will have their own costs and benefits. Without deeming these products to be subject to the FD&C Act, FDA would lack the authority to require manufacturers to provide, for example, vital ingredient and health information about them. We would also lack the authority to take regulatory action with respect to them, if we determined it was appropriate to do so.

The direct benefits of making each of the newly deemed tobacco products subject to the requirements of chapter IX of the FD&C Act are difficult to quantify, and we cannot predict the size of these benefits at this time. Among other effects, new products will be subject to an evaluation to ensure they meet the appropriate public health standard for the pathway before they can be marketed, labeling cannot contain misleading statements, and FDA will be made aware of the ingredients in newly deemed tobacco products. If, without the final rule, new products would pose substantially greater health risks than those already on the market, the premarket requirements made effective by this final rule would keep such products from appearing on the market and worsening the health effects of tobacco product use. The warning statements required by this final rule will help consumers better understand and appreciate the risks and characteristics of tobacco products.

The final rule as a whole will impose costs in the form of registration, submission, and labeling requirements. Manufacturers of newly deemed products, as well as some manufacturers of currently regulated products, will need to comply with the warning label provisions, which will impose additional costs, including costs for signs with warnings at point-of-sale for cigars sold singly without packaging. There will be potential costs for removing non-compliant point-of-sale advertising and complying with vending machine restrictions.

The primary estimate for the present value of total quantified costs over 20 years is approximately $988 million at a 3 percent discount rate and $817 million at a 7 percent discount rate. The quantified costs of the final rule can also be expressed as annualized values, as shown in table 1. Unquantified costs which may be attributable to this final rule include: Some consumer costs for users of the newly deemed products due to loss of product variety or higher prices; recordkeeping costs for exporters of deemed tobacco products; compliance costs for components and parts other than complete pipes, waterpipes, and ENDS delivery systems; the cost of testing and reporting for HPHCs; the cost of any clinical testing that may potentially be conducted to support SE reports; market adjustment (friction) costs and lost producer surplus associated with product consolidation, exit of manufacturers, and the switch to pure retailing among retailers such as vape shops who currently engage in manufacturing activities.

TABLE 5—SUMMARY OF QUANTIFIED COSTS OVER 20 YEARS ($ MILLION)

	Lower bound (3%)	Primary (3%)	Upper bound (3%)	Lower bound (7%)	Primary (7%)	Upper bound (7%)
Present Value of Private Sector Costs	517.7	783.7	1,109.8	450.4	670.9	939.8
Present Value of Government Costs [1]	204.6	204.6	204.6	145.7	145.7	145.7
Present Value of Total Costs	722.3	988.2	1,314.4	596.1	816.5	1,085.4
Annualized Value of Private Sector Costs	34.8	52.7	74.6	42.5	63.3	88.7
Annualized Value of Government Costs [1]	13.8	13.8	13.8	13.8	13.8	13.8
Annualized Value of Total Costs	48.5	66.4	88.3	56.3	77.1	102.5

[1] FDA costs represent an opportunity cost, but this rule will not result in changes to overall FDA accounting costs, the size of the federal budget, or the total amount of tobacco industry user fees.

Because it is not possible to compare benefits and costs directly when the benefits are not quantified, we employ a breakeven approach. For the reasons provided elsewhere in this preamble and in the analysis of impacts, FDA has concluded that the benefits of the final rule justify the costs.

In addition to the benefits and costs of this final rule, we assess the benefits and costs of four different approaches. These approaches consist of regulatory alternatives (*i.e.*, alternatives to the rule) as well as enforcement options (*i.e.*, periods of time during which FDA does not intend to enforce certain requirements). First, we assess the regulatory alternative of exempting premium cigars from regulation. Second, we assess two hybrid regulatory alternatives/enforcement options of providing either a 36-month or 12-month compliance period for labeling changes. Lastly, we assess the enforcement option of not extending the premarket review compliance policy to new flavored tobacco products (other than tobacco flavored products).[17] For the sake of simplicity only, we have referred to these four approaches as "alternatives to the rule."

In addition to the above alternatives, comments discussed changing the grandfather date as an alternative. FDA has decided not to include this option in the analysis of alternatives because we determined that the Agency lacks the authority to change the grandfather date.

Primary estimates of the costs of the regulatory alternatives appear as present values and annualized values in table 6.

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[17] Throughout the final RIA, any reference to "flavored tobacco products" means flavored products other than tobacco flavor.

TABLE 6—PRIMARY ESTIMATE OF QUANTIFIED COSTS FOR REGULATORY ALTERNATIVES (PRESENT AND ANNUALIZED VALUES, $ MILLION) [1]

Alternative	Present value (3%)	Present value (7%)	Annualized value (3%)	Annualized value (7%)
1—Exempt Premium Cigars from Regulation	959	794	64	75
2a—36-month compliance period for labeling changes	968	797	65	75
Final Rule and Compliance Period	988	817	66	77
2b—12-month compliance period for labeling changes	1,043	871	70	82
3—Do not extend the premarket review compliance policy to new flavored tobacco products	1,141	961	77	91

[1] Nonquantified benefits are described in the text.

In addition to the social costs described in this document, the final rule would lead to distributional effects, such as: Reduced revenues for firms in affected sectors, payment of user fees, and potential changes in tax revenues.

Domestic tobacco product manufacturers, tobacco product importers, and vape shops are the businesses primarily affected by this rule; most of these businesses are small. We focus the quantitative analysis of small entities on manufacturers and importers of cigars and ENDS products. We note that most pipe tobacco and waterpipe tobacco manufacturers and importers are also small, and we expect the impact on them to be similar to the impact on cigar manufacturers and importers. Even though user fees are a transfer payment and not a societal cost, they are a cost from the standpoint of the cigar and pipe manufacturers who must pay them under this final rule and have been included in the estimated burden for cigar manufacturers and importers. Estimated costs per cigar manufacturer or importer are $278,000 to $397,000 in the first year, $292,000 to $411,000 in the second year, and $235,000 to $257,000 in the third year. (The inclusion of user fees in these estimates will cause costs to be overstated for manufactures and importers who also manufacture currently regulated products. In addition, costs will vary by firm size as user fees are based on market share). Estimated costs per ENDS manufacturer or importer are $827,000 to $1.21 million in the first year, $832,000 to $1.21 million in the second year, and $22,000 to $64,000 in subsequent years. Although we do not quantitatively examine the financial effects on vape shops, we expect the proportion of vape shops that mix e-liquids may fall during the initial compliance policy period for submission and FDA receipt of PMTAs. After this initial compliance policy period, we expect that most vape shops will continue to operate but those that have not already switched pure retailing will likely do so. Regulatory alternatives that would reduce costs are analyzed as potential regulatory relief options for small businesses.

The Economic Analysis of Impacts of the final rule performed in accordance with Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act, and the Unfunded Mandates Reform Act is available at *http://www.regulations.gov* under the docket number(s) for this final rule (Ref. 204) and at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

XIX. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown in the following paragraphs with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products.

Description: On June 22, 2009, the President signed the Tobacco Control Act into law. In this rule, the Agency is extending FDA's "tobacco product" authorities in the FD&C Act to all other categories of products meeting the statutory definition of "tobacco product" in section 201(rr) of the FD&C Act, excluding accessories of deemed tobacco products. (Two options were presented in the NPRM. Under Option 1, all products meeting the definition of a "tobacco product," except accessories of newly deemed tobacco products, would be deemed. Option 2 was the same as Option 1, except a subset of cigars known as "premium cigars" would be excluded. After thorough review of the comments and the scientific evidence, FDA has concluded that Option 1 more effectively protects the public health and therefore has made that the scope of the final rule.) The rule also prohibits the sale of covered tobacco products to individuals under the age of 18 and prohibits the sale of covered tobacco products using the assistance of any retail-based electronic or mechanical device (such as a vending machine) except in facilities where the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time. The requirement that a retailer sell covered tobacco products in only a direct, face-to-face exchange without the assistance of electronic or mechanical devices is not intended to prevent the sale of tobacco products via the Internet, but the sale of covered tobacco products via any medium (including the Internet) must only be to persons 18 years of age or older.

The rule also provides that manufacturers, distributors, importers, and retailers are responsible for ensuring that the covered tobacco products (in addition to cigarettes and smokeless tobacco) they manufacture, label, advertise, package, distribute, import, sell, or otherwise hold for sale comply with all applicable requirements.

In addition, elsewhere in this issue of the **Federal Register**, FDA has made available a final guidance to provide information on how to establish and reference a Tobacco Product Master File (TPMF). TPMFs are expected to reduce the burden on applicants preparing premarket and other regulatory submissions because they can reference information in TPMFs rather than develop the information on their own.

Currently, FDA does allow for the submission and use of information to be incorporated by reference similar to master file programs for other FDA-regulated products.

A. Responses to Comments Regarding Proposed Collection of Information

1. Whether the Proposed Collection of Information Is Necessary for the Proper Performance of FDA's Functions, Including Whether the Information Will Have Practical Utility

(Comment 279) We received several comments regarding the practical utility of the information to be collected by FDA under the proposed regulations. The main concern among comments was that some of the requirements impose significant administrative burdens without generating useful information. Also, the comments believed that FDA is predicting that the paperwork burden will force almost all of the e-cigarette products to come off the market because manufacturers will go out of business.

(Response) FDA's regulation of the newly deemed products and the information the Agency is seeking will benefit the public health. As FDA discussed in the NPRM, deeming all tobacco products to be subject to chapter IX of the FD&C Act will provide FDA with critical information regarding the health risks of the products. FDA has not received any data indicating that regulation "will destroy almost all of the e-cigarette products on the market." We also note that FDA is announcing a compliance policy for small-scale tobacco product manufacturers, offering them targeted relief to address concerns that small manufacturers may need additional time to comply with certain requirements of the deeming rule, as discussed in section IV.D. This compliance policy will provide small-scale tobacco product manufacturers (*i.e.*, those manufacturers with 150 employees or fewer and $5,000,000 or less in annual revenues) with additional time to submit ingredient listing information (under section 904(a)(1)) and health documents (under section 904(a)(4)). This policy also provides that, for the first 30 months following the effective date of the rule, small-scale tobacco product manufacturers may receive extensions of time for providing responses to SE deficiency letters.

(Comment 280) One comment stated that FDA's proposed regulation is unnecessary and does not address any valid need in society. It also stated that the PRA should set limits on regulations that do not provide significant return to the U.S. population. Another comment asked that FDA not stifle advertisements, nor saddle the industry with unnecessary testing and reporting standards that stifle innovation and increase costs.

(Response) FDA disagrees with comments suggesting that FDA's rule will have such effects on industry or the nation. FDA finds that deeming tobacco products and applying the automatic provisions of the FD&C Act in accordance with this final rule will result in significant public health benefits and that the additional restrictions imposed by this rule are appropriate for the protection of the public health. For example, benefits that will arise as a result of deeming ENDS, including FDA review of premarket submissions/applications for new tobacco products in the United States pursuant to sections 905 and 910 of the FD&C Act, which will result in increased product consistency. FDA expects to receive premarket submissions/applications from ENDS manufacturers that will allow the Agency to determine whether a new product is substantially equivalent to a valid predicate product, exempt from SE., or appropriate for the protection of the public health.

2. Accuracy of FDA's Estimate of the Burden of the Proposed Collection of Information, Including the Validity of the Methodology and Assumptions Used

(Comment 281) Many comments argued that their products could be driven from the market due to the paperwork reporting requirements and FDA's authorization process. The comments claimed that many companies (particularly e-cigarette companies) lack experience or the systems in place to comply with the NPRM and that the premarket requirements would discourage the development of new products. They also said that requirements like labeling and registration would be unfeasible for small producers lacking the experience of navigating this regulatory environment.

(Response) FDA expects that the greater regulatory certainty created by the premarket review process will help companies to invest in creating novel products that benefit the health of the population as a whole, with greater confidence that the improved products in which they have invested will enter the market without having to compete against equally novel products that do not have to meet the same basic requirements. We also note that FDA is announcing a compliance policy for small-scale tobacco product manufacturers, offering them targeted relief in certain areas to address concerns that small manufacturers may need additional time to comply with certain requirements of the FD&C Act, as discussed in section IV.D. This compliance policy will provide small-scale tobacco product manufacturers (*i.e.*, those manufacturers with 150 employees or fewer and $5,000,000 or less in annual revenues) with additional time to submit ingredient listing information (under section 904(a)(1)) and health documents (under section 904(a)(4)). This policy also provides that, for the first 30 months following the effective date of the rule, small-scale tobacco product manufacturers may receive extensions of time for providing responses to SE deficiency letters.

(Comment 282) Several comments stated that the PMTA process imposes a number of burdens on manufacturers, the most onerous burden being the requirement for scientific investigations.

(Response) In the NPRM (79 FR 23142 at 23176), FDA included discussion intended to supplement and clarify the requirement for scientific investigations. As we noted, FDA expects that, in some cases, it will be possible for an applicant to obtain a PMTA marketing order without conducting new nonclinical or clinical studies where there is an established body of evidence regarding the public health impact of the product. Therefore, FDA believes that certain categories of PMTAs may not require significant financial and administrative resources associated with clinical investigations. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a draft guidance, which when final will provide the Agency's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products, including the need for "clinical studies" for the purposes of preparing PMTAs for ENDS. In addition, elsewhere in this issue of the **Federal Register**, FDA has made available a final guidance to provide information on how to establish and reference a Tobacco Product Master File. TPMFs are expected to reduce the burden on applicants preparing premarket and other regulatory submissions.

We also note that FDA is announcing an enforcement policy for small-scale tobacco product manufacturers, offering them targeted relief in certain areas to address concerns that smaller manufacturers may have, as discussed in section IV.D. This compliance policy will provide small-scale tobacco product manufacturers (*i.e.*, those manufacturers with 150 employees or fewer and $5,000,000 or less in annual revenues) with additional time to submit ingredient listing information (under section 904(a)(1)) and health documents (under section 904(a)(4)). This policy also provides that, for the first 30 months following the effective date of the rule, small-scale tobacco product manufacturers may receive extensions of time for providing responses to SE deficiency letters.

(Comment 283) Several comments expressed concern that FDA failed to provide any data on the number or type of e-cigarette businesses currently operating in the United States. According to the comments, there are at least 1,250 businesses. Other comments estimated that there are 14,000 to 16,000 e-cigarette retail outlets in the United States. They stated that these small manufacturing entities will not be able to participate in the PMTA process and most will go out of business.

(Response) At the time of the NPRM, FDA did not have precise estimates for ENDS products. Now that we have more data, the Agency is estimating the numbers for ENDS liquids and delivery systems elsewhere in the PRA section. As stated previously, FDA believes the TPMF process will help companies as they can reference information in TPMFs rather than develop the information on their own. Additionally, the enforcement policy for small-scale tobacco product manufacturers will assist small manufacturers. This compliance policy will provide small-scale tobacco product manufacturers (*i.e.*, those manufacturers with 150 employees or fewer and $5,000,000 or less in annual revenues) with additional time to submit ingredient reporting (under sections 904 and 915) and health documents (under section 904). This policy also provides that small-scale tobacco product manufacturers may receive extensions of time for providing responses to SE deficiency letters.

(Comment 284) Some comments noted that the NPRM made it appear that FDA would not allow any SE reports to be submitted for e-cigarette products, as there were only about a half dozen first generation e-cigarette products that were sold in the United States in February 2007 (the grandfather date), and those products are not substantially equivalent to any of today's products. Comments stated that applicants would then need to submit PMTAs and estimated that each PMTA would cost a successful applicant between $3 and $20 million.

(Response) The FD&C Act provides three pathways for obtaining FDA authorization to market a new tobacco product. Where a new product does not meet the requirements for SE exemption under section 905(j)(3) and does not have an appropriate predicate under section 905(j)(1)(A)(i) or is otherwise unable make a showing supporting a finding of SE., the manufacturer of the new product must submit a PMTA. As FDA stated in the NPRM, the Agency expects that some applicants may not need to engage in resource-intensive clinical investigations and provide long-term data to prepare and submit a complete PMTA. In addition, elsewhere in this issue of the **Federal Register**, FDA has made available draft guidance, which when final will describe FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products, including the need for clinical studies for the purposes of preparing PMTAs for ENDS.

(Comment 285) Several comments argued that FDA has greatly underestimated the total number of e-liquid products that are on the market. According to one comment, there are nearly 1,700 e-cigarette and e-liquid businesses on record, which does not include the many companies that manufacture hardware components used in ARPVs. One comment stated that a recent study found that greater than 34,000 different e-liquid products alone were sold on the Internet (*i.e.* 7,764 unique brand flavors averaging 4.4 different nicotine levels per brand) not including different vegetable glycerin/propylene glycol water levels or components in 466 identified different e-cigarette brands. Several comments estimated that there are 5,000 to 15,000 e-liquid producers and e-cigarette retail establishments in the United States. Other comments projected that there are at least 100,000 e-cigarette products currently on the market.

Similarly, some commenters felt that FDA grossly underestimated the number of responses for certain proposed information collections. For example, they noted that the NPRM states that FDA expects only 25 new product applications from e-cigarette manufacturers. They claimed that FDA has either miscalculated the number of distinct brands and types of e-cigarettes on the market, or the Agency expects most manufacturers to exit the market rather than submit product applications.

(Response) We have revised our estimates to reflect the most recent information available at the time of drafting this final analysis. FDA estimates the average number of vape shops that meet the definition of a manufacturer are 4,250. FDA also estimates that there will be 186 other manufacturers and 14 importers of ENDS products.

(Comment 286) Many comments said that FDA's estimates of the burdens imposed by the rule's information collection requirements are understated. Specifically, they stated that the Agency's estimates of the number of respondents in the category of "other tobacco, e-cigarettes, and nicotine product manufacturers," as well as the number of products on the market manufactured by these companies, were off by orders of magnitude.

(Response) Based on the comments and other evidence, FDA estimates there will be 186 manufacturers of ENDS products. Regarding the number of products, the number will depend on what type of submission is being sent to FDA. The burden charts in this section detail the current estimates FDA believes to be accurate.

(Comment 287) Some comments indicated that FDA equates the time and financial burden of preparing a PMTA with an SE application, but the PMTA requirements are significantly more burdensome than SE requirements, and it is completely unreasonable to allocate the same amount of man-hours needed to successfully complete a PMTA and an SE application.

(Response) The Agency has revised the estimated burden per PMTA response to an average of 1,500 hours to complete a PMTA. In reaching this average, FDA considered efficiencies achieved through manufacturer experience, application overlap, economies of scale, incorporation of evidence by reference, and other means including availability of the SE FAQ guidance. Based on this information, FDA believes an SE submission will take considerably less time and money. If the manufacturer is unable to show that its product is substantially equivalent to a predicate product or that its product is exempt from SE., then the manufacturer must submit a PMTA. The requirements of a PMTA may vary based on the type and complexity of the product.

(Comment 288) One comment said that FDA erred in its estimate of the in-house cost burdens imposed by the proposed information collections. The comment said internal costs can only be excluded when estimating the burden of an information collection if such costs are related to "usual and customary" activities. In this case, the comment believed FDA did not consider the types of internal costs that will be incurred by companies to comply with the information collections.

(Response) FDA disagrees with this comment. The Agency was thorough in its identification of usual and customary activities. The Agency used various existing data sources and considered all the costs associated with the collections of information. In reaching this average cost, FDA considered efficiencies achieved through manufacturer experience, application overlap, economies of scale, incorporation of evidence by reference, and other means.

(Comment 289) A few comments stated that most of the cost burden created by paperwork requirements will fall upon consumers, as hundreds of thousands of American consumers would lose access to what the comments state are "low-risk products" that have allowed consumers to quit smoking. They said FDA should take into consideration small business and consumer stakeholders' suggested alternatives to minimize the NPRM's potential impact.

(Response) FDA disagrees with these comments. This final rule will prevent new products from entering the market that are not appropriate for the protection of the public health, are not substantially equivalent to a valid predicate product, or are not exempt from SE. We also note that FDA is announcing a compliance policy for small-scale tobacco product manufacturers, offering them targeted relief in certain areas to address concerns that smaller manufacturers may need additional time to comply with certain requirements of the FD&C Act, as discussed in section IV.D. This compliance policy will provide small-scale tobacco product manufacturers (*i.e.*, those manufacturers with 150 employees or fewer and $5,000,000 or less in annual revenues) with additional time to submit ingredient listing information (under section 904(a)(1)) and health documents (under section 904(a)(4)). This policy also provides that, for the first 30 months following the effective date of the rule, small-scale tobacco product manufacturers may receive extensions of time for providing responses to SE deficiency letters.

(Comment 290) Several comments stated that FDA significantly underestimated the burden on the tobacco industry. The Agency estimated that 13,745 products will be affected by the NPRM and almost 90 percent of them were cigars and pipe tobacco. They noted that FDA estimated that up to 7,869 products will submit SE reports within the first 24 months after the rule is finalized, which they believed was very low, especially given the February 15, 2007, grandfather date.

(Response) FDA used available public information to estimate the burden on the tobacco industry and the comments did not provide empirical evidence of a different number of affected products. However, based on experience with currently regulated products and changes in the industry we have revised the burden accordingly. The Agency also finds that these comments have not provided evidence as to why the grandfather date will cause applicants to submit more SE applications than FDA estimated.

(Comment 291) One comment argued that FDA has greatly underestimated the number of premium cigar products that will be subject to premarket review. According to the comment, premium cigar makers are distinct from other tobacco product manufacturers in the number of products they market and the volume of those lines. This comment stated that the average number of cigars produced for any given product in a year is 32,655, with 33.6 percent of reported annual production rates at or below 10,000 units.

Several other comments argued that the typical premium cigar manufacturer may have over 100 unique stock keeping units (SKUs) and typically will turn over about 15 percent of those SKUs in any given year. Their data indicates there are at least 10,000 and maybe as many as 20,000 unique SKUs in the United States, which would add to FDA's workload for evaluating new product applications. They also estimated that the premium hand-rolled cigar category alone could generate numbers in excess of 10,000 new product applications.

Other comments stated that the premarket application process will be costly and time consuming for cigar manufacturers and will likely result in many different kinds of newly deemed tobacco products being removed from the marketplace. The constant variation in the cigar tobacco used to make premium cigars will create significant regulatory burdens and costs for cigar manufacturers to be constantly submitting premarket applications. Comments stated that cigar manufacturers that are unable to bear the cost of applications will cease bringing new products to the marketplace.

The comments expressed similar concerns regarding e-cigarettes, stating that each e-cigarette manufacturer would need to submit a PMTA for every brand of e-cigarette currently being sold and new e-cigarettes introduced into the marketplace. Small manufacturers may not have the financial resources to submit PMTAs, which will result in the removal of e-cigarettes from the marketplace. The end result of the PMTA process will be a significant negative impact on small businesses.

(Response) The FD&C Act provides for three marketing pathways for new tobacco products—SE to a valid predicate product, exemption from SE., and PMTA. If the manufacturer is unable to show that its product is substantially equivalent to a valid predicate product or that its product is exempt from SE., then the firm must submit a PMTA. The requirements and costs of a PMTA may vary based on the type and complexity of the product. For example, where there is limited understanding of a product's potential impact on public health, several nonclinical and clinical studies may be required for market authorization. In such case, the requirements and cost of the PMTA likely would be higher than for a product in which there is already substantial scientific data on the potential public health impact.

(Comment 292) Many comments noted that FDA included a small number of PMTAs for e-cigarette products in its analysis. Some comments stated that if this is the case, FDA's estimates would probably include only a fraction of the products that are believed to be used to stop smoking cigarettes. They commented that the cost burdens of the paperwork requirements will result in an unnecessary price increase for the consumer and the PMTA requirements will limit the availability of e-cigarettes to addicted smokers trying to quit. Their concern is the burden of the paperwork would fall on both merchants and consumers.

(Response) FDA disagrees with these comments. The Agency's intention is not to impose additional costs to consumers but, instead, to prevent new products from entering the market that are not appropriate for the protection of the public health, are not substantially equivalent to a predicate product, or are not exempt from SE. Per Agency experience and updates in the industry, FDA has updated the number of ENDS products we estimate will submit a PMTA.

(Comment 293) Some comments disagreed with FDA's estimate that it expects only one "other tobacco, e-cigarette and nicotine product manufacturers" respondent to submit an annual health and toxicological report and its estimate that there would only be one respondent to self-certify that its product does not contain nicotine. They stated that there may be hundreds of e-liquid manufacturers self-certifying for use of the alternative statement, because it is standard industry practice to offer 0 milligram nicotine flavors in vials.

(Response) At this time, we do not have sufficient evidence to warrant revising the burden estimates.

(Comment 294) Many comments stated that FDA's estimates do not reflect the realities of the market and FDA's estimates assume that most of these small companies will be forced to exit the industry because of the high compliance and paperwork burdens envisioned by the NPRM. However, others believed that as the market evolves, many companies will continue to operate and comply with FDA's regulations.

Further, many other comments stated that, at best, FDA's estimate that there are only 140 to 188 potential respondents in the category of "other tobacco, e-cigarettes, and nicotine product manufacturers" is "egregiously off target" based on the available evidence. They believed that the entire industry will be eliminated as a result of the regulatory and paperwork burdens in the NPRM. They also noted that the reason for the difference between 140 and 188 in the Analysis of Impacts and PRA sections is unclear.

(Response) There is a high level of uncertainty in the number of manufacturers of ENDS. FDA is required to estimate burden as part of the PRA analysis. As many comments describe, the industry is ever changing; during the time that the NPRM was in review, and since the NPRM was published, the ENDS industry has grown. The comments on the number of ENDS manufacturers provided industry estimates rather than concrete data sources. In the case of non-retail manufacturers, the comment did not always specify whether the cited numbers included both domestic and foreign manufacturers, or only domestic manufactures. Therefore, considerable uncertainty remains as to the number of domestic non-retail manufacturers. Similarly, the comments did not address the number of non-retail importers. In the Regulatory Impact Analysis (RIA) for this final rule, based on logo counts from trade association Web sites and FDA listening sessions, it is estimated that there are 168 to 204 formal manufacturers of ENDS products (not including ENDS retail establishments that meet the definition of a manufacturer). For the PRA analysis, we took the average for a total of 186 manufacturers. We also estimate that there are 14 importers of ENDS products.

(Comment 295) Many comments stated that it would not be possible to complete a PMTA within 24 months after the effective date of the final rule and that it is an insufficient amount of time for manufacturers to conduct any required clinical studies in support of a PMTA.

(Response) As stated throughout this document, FDA is providing a 24-month compliance period for manufacturers to submit (and for FDA to receive) a PMTA. If manufacturers submit the appropriate applications during this compliance period, FDA will not enforce against those manufacturers continuing to market their products without FDA authorization for a certain time period. For products using the PMTA pathway, this compliance period closes 36 months after the effective date. Once the continued compliance period ends, FDA intends to actively monitor and enforce the premarket authorization requirements regarding products on the market without authorization even if the respective submission is still under review. As noted previously, FDA expects that, in some cases, it will be possible for an applicant to obtain a PMTA order without conducting any new nonclinical or clinical studies where there is an established body of evidence regarding the public health impact of the product. Therefore, FDA believes that many PMTAs may not require significant administrative resources associated with clinical investigations.

(Comment 296) Several comments noted that if FDA requires health documents from manufacturers and importers of newly deemed tobacco products, the Agency should establish a similar production timeline as it did for currently regulated products (*i.e.,* cigarettes, cigarette tobacco, smokeless tobacco, and roll-your-own tobacco) and only require production of health documents developed during the 6-month period following the effective date of the regulation.

(Response) As stated in the compliance date tables, the compliance period for manufacturers of products currently on the market to submit health documents is 6 months after the effective date of the final rule. Manufacturers of products entering the market after the effective date of the final rule must comply within 90 days before delivery of the product for introduction into interstate commerce. With this final rule, FDA also is announcing that it will extend the compliance period for an additional 6 months from the effective date to allow small-scale tobacco product manufacturers time to organize, compile, and digitize documents. Additionally, as stated elsewhere, FDA generally does not intend to take enforcement action regarding the submission of all such documents at this time so long as a specified set of documents are submitted by [the effective date plus 6 months]. FDA will publish additional guidance that specifies the scope of such documents with sufficient advance time for manufacturers and importers to prepare their submissions.

(Comment 297) Some comments stated that FDA has underestimated the number of other tobacco product manufacturers that will submit the required health documents.

(Response) FDA based this burden estimate on the existing collection that applies to tobacco products currently subject to the FD&C Act and FDA experience. The comments did not provide a basis or an estimate of other tobacco product manufacturers for FDA to utilize in its review, and the Agency is not aware of any information that warrants changing this estimate. We note that at this time, FDA intends to limit enforcement to finished tobacco products. A finished tobacco product refers to a tobacco product, including all components and parts, sealed in final packaging intended for consumer use (*e.g.,* filters, filter tubes, e-cigarettes, or e-liquids sold separately to consumers or as part of kits). FDA does not at this time intend to enforce this requirement for components and parts of newly deemed products that are sold or distributed solely for further manufacturing into finished tobacco products. However, any component or part of a newly deemed tobacco product that is sold directly to consumers as a "finished tobacco product" will be required to comply with the premarket review requirements discussed throughout this document.

(Comment 298) Some comments stated that e-liquid companies should be allowed to amend their ingredient lists if they add or remove ingredients or increase the maximum concentration of any of their current ingredients in any of their products, rather than submit a new ingredient list for the new product.

(Response) Ingredient listings contain important data that enable FDA to gain better understanding of the contents of regulated products. This information will assist FDA in assessing potential health risks and determining if future regulations to address these health risks are warranted. In addition, when an e-liquid manufacturer adds or removes ingredients from a product, it becomes a "new tobacco product."

(Comment 299) Several comments disagreed with FDA's proposed premarket review burdens for pipe tobacco manufacturers. At least one comment indicated that FDA's proposed estimate that it will receive only one new product application for pipe tobacco products grossly underestimates the number of brands of pipe tobacco that have entered the market since 2007 or indicates that the Agency expects all but one manufacturer to voluntarily stop production of new pipe tobacco products without submitting an SE report or PTMA application. In addition, the comments stated that pipe tobacco manufacturers will incur cost and time burdens if they are required to submit PMTAs for each new blend of pipe tobacco that they manufacture, including millions of dollars per year in research to prepare the PMTAs.

(Response) At this time, FDA finds there is insufficient evidence to increase the burden estimates. FDA believes that pipe tobacco manufacturers will utilize the SE and SE exemption pathways. We believe they are manufactured similarly with few, if any, modifications and many of the ingredients and suppliers are the same as those utilized in previous years.

(Comment 300) Several comments pointed out inconsistencies between the PRA and Analysis of Impacts sections in the NPRM. They noted that the Analysis of Impacts clearly states that FDA does not have an estimate of e-cigarette entities that would register with FDA. If FDA could not estimate the number of affected entities in the Analysis of Impacts, they believed this should also be reflected in the PRA section. In addition, they stated that the estimated number of PMTAs (25) in the PRA section contradicts the number of estimated PMTAs in the Analysis of Impacts.

(Response) The RIA and PRA analyses are conducted to fulfill different purposes and must adhere to different requirements; as a result, the two analyses would rarely, if ever, be the same. For example, the time horizons for the analyses are typically different. Information collections are approved for a up to a 3-year period and are reanalyzed every time they are up for extension, whereas a prospective RIA is conducted before a rule is issued using a time horizon chosen to capture the most important effects of the rule (generally 20 years). If estimates differ from year to year, the RIA will often explicitly identify how the estimates vary, whereas the PRA analysis will most often use an average or the estimate for the current year. Regulatory impact analyses also tend to make more frequent use of ranges rather than point estimates.

As referenced previously, there is a high level of uncertainty in the number of manufacturers for ENDS. In the RIA for this final rule, based on logo counts from trade association Web sites and FDA listening sessions, it is estimated that there are 168 to 204 formal manufacturers of ENDS products. For the PRA analysis, we took the average of 168 and 204 for a total of 186 manufacturers. We also estimate that there are 14 importers of ENDS products.

(Comment 301) A number of comments also noted that FDA should be required to estimate and report the full social costs of eliminating what they considered to be beneficial products from the market where the manufacturers are unable to afford the PMTA costs.

(Response) FDA is not aware of any evidence indicating that such social costs will accrue. Nevertheless, such estimates are outside the scope of the PRA analysis.

3. Ways To Enhance the Quality, Utility, and Clarity of the Information To Be Collected

(Comment 302) One comment stated that FDA has not consulted with industry nor has the Agency audited industry recordkeeping to support the assumption that manufacturers have enough information to prepare SE reports.

(Response) FDA's proposed burden estimates are based on information available at the time of preparing the NPRM. If interested parties have evidence that warrants revising these burden estimates, they were requested to submit such evidence during the comment period for FDA to take into account when preparing final burden estimates.

(Comment 303) One comment recommended that the Office of Information and Regulatory Affairs (OIRA) should void the proposed regulations as they relate to e-cigarettes, that OIRA and FDA should urge Congress to work with FDA to create a new regulatory framework for e-cigarettes, and, at the very least, that OIRA require that FDA prepare new estimates of the paperwork burdens.

(Response) FDA disagrees with this comment. FDA has estimated the PRA burdens with the best evidence that is currently available. In addition, as stated in the NPRM and throughout this final rule, the deeming provisions are beneficial to the public health and the additional provisions are appropriate for the protection of the public health.

4. Ways To Minimize the Burden of the Collection of Information on Respondents, Including Through the Use of Automated Collection Techniques, When Appropriate, and Other Forms of Information Technology

(Comment 304) One comment asserted that, under the PRA, a review of regulations should include an attempt to ensure that the paperwork is not unduly burdensome. The comment also stated that FDA appears to be ignoring the greatest cost of the paperwork burden (*i.e.*, most manufacturers will find the paperwork burden to be so great that they will abandon products or their entire businesses without attempting to comply with the requirements). They argued that FDA should follow the requirements as stated in the PRA and limit data collection to information that is useful and dependable.

(Response) FDA disagrees with this comment. FDA has faithfully complied with the all aspects of the PRA and any other applications laws and regulations.

B. Existing Burdens Associated With Tobacco Products Currently Subject to the FD&C Act (i.e., Cigarettes, Cigarette Tobacco, Roll-Your-Own Tobacco, and Smokeless Tobacco) With Approved OMB Control Numbers

The information collection requirements referenced in this section are amending currently approved information collections. Once the rule is finalized, the associated collections of information will be submitted to OMB for approval as revisions to the currently approved information collections. After submission to OMB, the revised collections and associated documents can be viewed at OMB's public Web site (*http://www.reginfo.gov*).

The burden estimates found in this section include existing collections that have been approved by OMB and cover tobacco products that are currently subject to the FD&C Act (*i.e.*, cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco). In developing the burden estimates for newly deemed tobacco products, FDA based the estimates on the existing collections that currently cover cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco.

1. Tobacco Product Establishment Registration and Submission of Certain Health Information (OMB Control Number 0910–0650)

Description of Respondents: The respondents to this collection of information are manufacturers or importers, or agents thereof, of new and currently regulated tobacco products who are required to make submissions to FDA under section 904 of the FD&C Act, including the submission of an initial list of all ingredients in their tobacco products and the submission of information whenever additives or their quantities are changed. The respondents to this collection are also persons engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products who must register their establishments and submit a list of all tobacco products being manufactured, prepared, compounded, or processed by that person for commercial distribution at the time of registration under section 905 of the FD&C Act.

Section 101 of the Tobacco Control Act amended the FD&C Act by adding sections 905 and 904. Section 905(b) of the FD&C Act requires that every person who owns or operates any establishment in any State engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products register with FDA the name, places of business, and all establishments owned or operated by that person. Section 905(i)(1) of the FD&C Act requires that all registrants, at the time of registration, must submit to FDA a list of all tobacco products that are being manufactured, prepared, compounded, or processed by that person for commercial distribution, along with certain accompanying consumer information and other labeling for such products and a representative sampling of advertisements.

If an ENDS retail establishment engages in these activities, it will be required to register and list their products with FDA. These requirements apply under the statute for all distinct products manufactured, and they enable FDA to assess the landscape of products manufactured by these entities. If ENDS retail establishments are custom mixing e-liquids and/or other ENDS products or components, then they will have to list each combination that they sell. For such establishments to continue to engage in mixing after this rule becomes effective, they would need to satisfy the requirements for manufacturers and the premarket authorization of new tobacco products as a result of this final rule. We note, however, that FDA does not intend to enforce the premarket authorization requirements during staggered compliance periods following the effective date, as stated previously in this preamble to this rule.

Section 904(a)(1) of the FD&C Act requires each tobacco product manufacturer or importer, or agent thereof, to submit a listing of all ingredients, including tobacco, substances, compounds, and additives that are added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand and by quantity in each brand and subbrand. Section 904(c) of the FD&C Act also requires submission of information whenever additives or their quantities are changed.

As previously referenced in section IV, for small-scale tobacco product manufacturers, FDA is providing a one-time allowance of an additional 6 months after the effective date of this final rule for initial reporting of ingredients. This regulatory relief is only for small-scale tobacco product manufacturers.

FDA issued guidance documents on both (1) Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments (74 FR 58298, November 12, 2009) and (2) Listing of Ingredients in Tobacco Products (74 FR 62795, December 1, 2009) to assist persons making these submissions to FDA under the FD&C Act. Although electronic submission of registration, product listing, and ingredient listing information are not required, FDA strongly encourages electronic submission to facilitate efficiency and timeliness of data management and collection. To that end, FDA designed the eSubmitter application, and then the FDA FURLS, to streamline the data entry process for registration, product listing, and ingredient listing. This tool allows for importation of large quantities of structured data, attachments of files (*e.g.*, in PDFs and certain media files), and automatic acknowledgement of FDA's receipt of submissions. FDA also developed paper forms (Form FDA 3741—Registration and Listing for Owners and Operators of Domestic Tobacco Product Establishments and Form FDA 3742—Listing of Ingredients in Tobacco Products) as alternative submission tools. Both the FURLS and the paper forms can be accessed at *http://www.fda.gov/tobacco*. FDA estimates the additional annual burden for the information collection as a result of this rule as follows:

TABLE 7—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	Number of respondents	Number of responses per respondent[2]	Total annual responses	Average burden per response (in hours)	Total hours
Tobacco Product Establishment Initial First Year Registration (electronic and paper submission):					
Cigar Entities (Including Large and Small, and Importers).	221	1	221	2	442
Pipe and Waterpipe Tobacco Entities (Including Importers (22)).	96	1	96	2	192
Other Tobacco, E-Cigarettes, and Nicotine Product Entities and ENDS Products Importers (7)[3].	193	1	193	2	386
Vape shops that qualify as manufacturers[4]	4,250	1	4,250	2	8,500
Total Tobacco Product Establishment Initial First Year Registration.					9,520
Tobacco Product Establishment Recurring Registration (electronic and paper submission):					
Cigar Entities (Including Large and Small, and Importers).	221	1	221	0.20 (12 minutes)	44
Pipe and Waterpipe Tobacco Entities (Including Importers (22)).	96	1	96	0.20 (12 minutes)	19
Other Tobacco, E-Cigarettes, and Nicotine Product Entities and ENDS Products Importers (7)[3].	193	1	193	0.20 (12 minutes)	39

TABLE 7—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

Activity	Number of respondents	Number of responses per respondent[2]	Total annual responses	Average burden per response (in hours)	Total hours
Vape shops that qualify as manufacturers[4]	4,250	1	4,250	0.20 (12 minutes)	850
Total Tobacco Product Establishment Recurring Registration.					952
Tobacco Product Listing Initial First Year (electronic and paper submission):					
Cigar Entities (Including Large and Small, and Importers).	221	1	221	2	442
Pipe and Waterpipe Tobacco Entities (Including Importers (22)).	96	1	96	2	192
Other Tobacco, E-Cigarettes, and Nicotine Product Entities and ENDS Products Importers (7))[3].	193	1	193	2	386
Vape shops that qualify as manufacturers[4]	4,250	1	4,250	2	8,500
Total Hours Tobacco Product Listing Initial First Year.					9,520
Tobacco Product Listing Recurring (electronic and paper submission):					
Cigar Entities (Including Large and Small, and Importers).	221	2	442	0.40 (24 minutes)	177
Pipe and Waterpipe Tobacco Entities (Including Importers (22)).	96	2	192	0.40 (24 minutes)	77
Other Tobacco, E-Cigarettes, and Nicotine Product Entities and ENDS Products Importers (7)[3].	193	2	386	0.40 (24 minutes)	154
Vape shops that qualify as manufacturers[4]	4,250	2	8,500	0.40 (24 minutes)	3,400
Total Hours Tobacco Product Listing Recurring.					3,808
Obtaining a Dun and Bradstreet (DUNS) Number:					
Cigar Entities (Including Large and Small, and Importers).	221	1	221	0.5 (30 minutes)	111
Pipe and Waterpipe Tobacco Entities (Including Importers (22)).	96	1	96	0.5 (30 minutes)	48
Other Tobacco, E-Cigarettes, and Nicotine Product Entities and ENDS Products Importers (7)[3].	193	1	193	0.5 (30 minutes)	97
Vape shops that qualify as manufacturers[4]	4,250	1	4,250	0.5 (30 minutes)	2,125
Total Hours Obtaining DUNS Number					2,381
Total Hours Registration, Product Listing, and DUNS Number.					26,181
Tobacco Product Ingredient Listing (electronic and paper submission):					
Cigar Entities (Including Large and Small, and Importers).	329	5.38	1,770	3	5,310
Pipe and Waterpipe Tobacco Entities (Including Importers (43)).	117	20.62	2,413	3	7,239
Other Tobacco, E-Cigarettes, and Nicotine Product Entities and ENDS Products Importers (7)[3].	200	11.40	2,280	3	6,840
Vape shops that qualify as manufacturers[4]	4,250	11.73	49,853	1	49,853
Total Hours Submitting Product Ingredient Listing.					69,242
Total Burden Tobacco Product Establishment Registration and Submission of Certain Health Information.					121,604

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

[2] This number is estimated to be the total annual responses divided by the number of respondents, rounded to the nearest tenth.

[3] Importers are included throughout this Table 7 to the extent that they engage in the manufacture, preparation, compounding, or processing of tobacco products, which includes repackaging or otherwise changing the container, wrapper, or labeling of any tobacco product package in furtherance of the distribution of the tobacco product from the original place of manufacturer to the person who makes final delivery or sale to the ultimate consumer or use.

[4] FDA assumes that vape shops will register and list only during the first two years after the rule becomes effective.

Based on aggregate information obtained from the TTB, in 2013 there were 113 domestic manufacturers of cigars, 216 importers of cigars, 74 manufacturers of pipe (including waterpipe) tobacco, and 43 importers of pipe (including waterpipe) tobacco who will be required to register under section 905 of the FD&C Act. For the purposes of this analysis, FDA estimates that the majority of the 4,250 vape shops that qualify as manufacturers will only register and list in the first two years after the rule becomes effective. In addition, FDA estimates that 186 ENDS manufacturers will be required to register under section 905 of the FD&C Act.

Product listing information is provided at the time of registration. Currently, registration and listing requirements only apply to domestic establishments engaged in the manufacture, preparation, compounding, or processing of a tobacco product. This includes importers to the extent that they engage in the manufacture, preparation, compounding, or processing of a tobacco product, including repackaging or otherwise changing the container, wrapper, or labeling of any tobacco product package.[18] Foreign establishments are not required to register and list until FDA issues regulations establishing such requirements in accordance with section 905(h) of the FD&C Act. To account for the foregoing, we include both domestic manufacturing establishments and importers in our estimates. Specifically, for the PRA analysis, we have used the midpoint between TTB permit counts for manufacturers and permit counts for manufacturers and importers as a likely overestimate of the number of entities that need to comply with registration and product listing (The Analysis of Impacts includes importers in the upper bound.)

The PRA burden estimates have been updated to fully incorporate the use of an electronic system known as FURLs for submitting registration and product listing information to FDA. With the FURLs system, manufacturers can enter information quickly and easily. For example, product label pictures can be uploaded directly and we anticipate that most, if not all companies, already have electronic versions of their labels for printing, sales, or marketing purposes. We anticipate that initial entity registration will take 2 hours and initial product listing will take an additional 2 hours per entity.

FDA estimates that the initial first year submission of registration information required by section 905 of the FD&C Act will take 2 hours per establishment, with a total of 4,760 establishments that will be required to register under this rule, for a total of 9,520 hours (4,760 × 2).

The estimate for the number of product listing submissions for cigars is derived by using product counts from two retail Web sites: *http://www.cigarsinternational.com/* and *http://www.pipesandcigars.com/*. These two large Internet retailers had larger product offerings than other sites reviewed and sell both mass-market and specialty products. Estimates of product formulations and product-package combinations for cigars are centered over the product counts from the two Web sites. To derive the product listing count for pipe tobacco, we count the products on a Web site with a broad product offering, *http://www.pipesandcigars.com/*. We estimate formulations with the number of the product names and product-packages with the number of product-package combinations. FDA derives the product listing estimate for ENDS products by consulting experts at FDA's CTP who cataloged the ENDS products currently available on five Web sites and in scanner data from Nielsen. FDA estimates that the initial first year submission of product listing information required by section 905 of the FD&C Act will take 2 hours per submission for 4,760 submissions/annual responses for a total of 9,520 hours.

Once information is entered into FURLs, the twice yearly confirmation of annual registration and product listing updates is simplified as all information previously entered is maintained in the system. Therefore, we expect the recurring burden of subsequent years for updating registration and product listing information will take 1 hour annually per establishment (12 minutes for registration and 48 minutes for product listing). The total hours are 4,760 (952 updating registration and 3,808 product listing).

FDA estimates that obtaining a DUNS number will take 30 minutes. FDA assumes that all the establishment facilities that will be required to register under section 905 of the FD&C Act would obtain a DUNS number, with a total of 4,760 establishments that would need to obtain this number. The total burden to obtain a DUNS number is 26,181 hours.

FDA estimates that the submission of ingredient listing information as required by section 904 of the FD&C Act will take 3 hours per tobacco product based on the estimates found in the existing collection. The Agency estimates that approximately 56,316 ingredient listings/annual responses will be submitted annually based on the methodology used for estimating the number of product listing submissions described in this section. The total ingredient listing reporting is 69,242 hours. FDA estimates that the total burden for tobacco product establishment registration and ingredient listing reporting is 121,604 hours.

2. Tobacco Health Document Submission (OMB Control Number 0910–0654)

Description of Respondents: Respondents to this collection of information are tobacco product manufacturers or, importers, or agents thereof, who will submit all documents to FDA developed after June 22, 2009, that relate to health, toxicological, behavioral, or physiologic effects of current or future tobacco products. As stated elsewhere, however, FDA generally does not intend to take enforcement action regarding the submission of all such documents at this time so long as a specified set of documents are submitted by [the effective date plus 6 months]. FDA will publish additional guidance that specifies the scope of documents that manufacturers and importers will be required to submit by [the effective date plus 6 month], with sufficient advance time for manufacturers and importers to prepare their submissions.

Section 904(a)(4) of the FD&C Act requires each tobacco product manufacturer or importer, or agent thereof, to submit all documents to FDA developed after June 22, 2009, that relate to health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives (tobacco health documents). To address concerns of certain small businesses relating to the tobacco health documents requirement, FDA is extending the compliance period for small-scale tobacco product manufacturers for an additional 6 months following the end of the generally applicable compliance period to allow submitters time to organize, compile, and digitize documents.

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[18] Under the Internal Revenue Code, the manufacture, preparation, compounding, or processing of a tobacco product may require a permit as a manufacturer of tobacco products. As we understand TTB's permitting requirements, entities lacking a manufacturer permit, including importers, may not engage in any of the listed activities, including repackaging tobacco products after such products are released from customs custody. It is unclear whether TTB would require a manufacturer permit for *all* activities for which FDA would determine the entity must register and list; because there may be some entities with import permits for which FDA would conclude registration is necessary, FDA includes those numbers as part of its upper-bound estimate of affected entities.

FDA is collecting the information submitted under section 904(a)(4) of the FD&C Act through an electronic portal and through a paper form (Form FDA 3743) for those individuals who choose not to use the electronic portal.

FDA estimates the additional annual burden for the information collection as a result of this rule as follows:

TABLE 8—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Cigar Manufacturers (Including Large and Small)	2	4	8	50	400
Pipe and Waterpipe Tobacco Manufacturers	1	4	4	50	200
Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers ENDS	1	4	4	50	200
Importers of Cigars and Pipe Tobacco Who Are Considered Manufacturers	1	4	4	50	200
Importers of Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers ENDS	1	4	4	50	200
Total Hours Health Document Submission					1,200

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA estimates that a tobacco health document submission for cigars, pipe and waterpipe tobacco, other tobacco, tobacco importers, and importers of ENDS required by section 904(a)(4) of the FD&C Act, will take approximately 50 hours per submission based on the existing collection that applies to tobacco products currently subject to the FD&C Act and FDA experience. To derive the number of respondents for this provision, FDA assumes that very few manufacturers or importers, or agents thereof, would have health documents to submit. Therefore, the Agency estimates that approximately six submissions (two for cigar manufacturers, one for pipe and waterpipe tobacco manufacturers, one for other tobacco product manufacturers, and one for tobacco importers, and one for importers of ENDS who are considered manufacturers) will be submitted on an annual basis. FDA estimates the total number of hours is 1,200 hours (6 submissions multiplied by 4 times per year multiplied by 50 average burden hours).

3. Exemptions From Substantial Equivalence Requirements (OMB Control Number 0910–0684)

Description of Respondents: Respondents to this collection of information are manufacturers of deemed tobacco products who are requesting an exemption from the SE requirements of the FD&C Act.

In a final rule that published on July 5, 2011, FDA established procedures for manufacturers to request exemptions from the SE requirements of the Tobacco Control Act (SE exemptions final rule). The SE exemptions final rule was issued under section 905(j)(3) of the FD&C Act, which provides that FDA may exempt from the requirements relating to the demonstration of SE tobacco products that are modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive, if FDA determines that: (1) Such modification would be a minor modification of a tobacco product that can be sold under the FD&C Act, (2) a report is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for protection of the public health, and (3) an exemption is otherwise appropriate.

The exemption request may be made only by the manufacturer of a legally marketed tobacco product for a minor modification to that manufacturer's product, and the request (and supporting information) must be submitted in an electronic format that FDA can process, review, and archive. In addition, the request and all supporting information must be legible and in (or translated into) the English language.

An exemption request must be submitted with supporting documentation and contain:

- The manufacturer's address and contact information;
- identification of the tobacco product(s);
- a detailed explanation of the purpose for the modification;
- a detailed description of the modification, including a statement as to whether the modification involves adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive;
- a detailed explanation of why the modification is a minor modification of a tobacco product that can be sold under the FD&C Act;
- a detailed explanation of why a report under section 905(j)(1)(A)(i) intended to demonstrate SE is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for the protection of the public health;
- a certification summarizing the supporting evidence and providing the rationale for why the modification does not increase the tobacco products appeal to or use by minors, toxicity, addictiveness, or abuse liability;
- other information justifying an exemption; and
- an environmental assessment under part 25 (21 CFR part 25) prepared in accordance with § 25.40.

This information will enable FDA to determine whether the exemption request is appropriate for the protection of the public health. There is also a procedural mechanism for rescinding an exemption if FDA finds the exemption is not appropriate for the protection of the public health. In general, FDA will rescind an exemption only after providing the manufacturer notice of the rescission and an opportunity for an informal hearing under part 16 (21 CFR part 16). However, FDA may rescind an exemption prior to notice and opportunity for a hearing under part 16 if the continuance of the exemption presents a serious risk to public health. In that case, FDA would provide the manufacturer an opportunity for a hearing as soon as possible after the rescission.

FDA reviews the information submitted in support of the request and determines whether to grant or deny the request based on whether the criteria specified in the statute are satisfied. FDA may request additional information from the manufacturer if necessary to make the determination. If the manufacturer fails to respond within the timeframe requested, FDA will consider the exemption request withdrawn.

FDA estimates the additional annual burden for the information collection as a result of this rule as follows:

TABLE 9—ESTIMATED ANNUAL REPORTING BURDEN (WHEN MANUFACTURERS CHOOSE TO SEEK EXEMPTION FROM SUBSTANTIAL EQUIVALENCE) [1]

21 CFR Section and activity	Number of respondents	Number of responses per respondent [2]	Total annual responses	Average burden per response (in hours)	Total hours
§ 1107.1(b) Optional Preparation of Tobacco Product Exemption From Substantial Equivalence Request Including § 25.40 Preparation of an Environmental Assessment					
Cigar Manufacturers (Including Large, Small, and Importers)	196	1	196	24	4,704
Pipe and Waterpipe Tobacco Manufacturers (Including Importers)	105	1	105	24	2,520
Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers (ENDS and Delivery Systems (Including Importers))	18	1	18	24	432
Total Hours (§ 1107.1(b))	....	....	....	....	7,656
§ 1107.1(c) Preparation of Additional Information for Tobacco Product Exemption From Substantial Equivalence Request:					
Cigar Manufacturers (Including Large, Small, and Importers)	59	1	59	3	177
Pipe and Waterpipe Tobacco Manufacturers (Including Importers)	32	1	32	3	96
Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers (ENDS and Delivery Systems (Including Importers))	3	1	3	3	9
Total Hours (§ 1107.1(c))	....	....	....	....	282
Section 905(j)(1)(A)(ii) of the FD&C Act: If exemption granted, report submitted to demonstrate tobacco product is modified under section 905(j)(3), modifications are to a product that is commercially marketed and compliant, and modifications covered by exemptions granted by Secretary under section 905(j)(3):					
Cigar Manufacturers (Including Large, Small, and Importers)	293	1	293	3	879
Pipe and Waterpipe Tobacco Manufacturers (Including Importers)	156	1	156	3	468
Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers (ENDS and Delivery Systems (Including Importers))	26	1	26	3	78
Total Hours (section 905(j)(1)(A)(ii))	....	....	....	....	1,425
Total Hours Exemptions From Substantial Equivalence Requirements	....	....	....	....	9,363

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

[2] This number is estimated to be the total annual responses divided by the number of respondents, rounded to the nearest hundredth.

The estimated average burden per response (in hours) is based on the burdens associated with the existing information collection that applies to tobacco products currently subject to the FD&C Act (*i.e.*, cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco). FDA estimates that we will receive 319 exemption requests under § 1107.1(b) for 24 hours per response including EA for a total of 7,656 hours. Since an EA is required for each § 1107.1(b) (Optional Preparation of Tobacco Product Exemption From Substantial Equivalence Request), the burden per response for EAs (12 hours) has been combined with the 12 hours for an SE request for a total of 24 hours.

FDA estimates, based on the existing information collection that applies to tobacco products currently subject to the FD&C Act, we will receive 94 submissions requiring additional information in support of the initial exemption request, and it is expected that it will take an average of 3 hours to prepare the additional information for a total of 282 hours.

FDA estimates that 475 respondents will prepare 475 responses and each response will take approximately 3 hours to prepare, as required by section 905(j)(1)(A)(ii), for a total of 1,425 hours. This collection of information requires a manufacturer to submit a report at least 90 days prior to making an introduction or delivery for introduction into interstate commerce for commercial distribution of a tobacco product. Section 905(j)(1)(A)(ii) of the FD&C Act states that if an exemption has been requested and granted, the manufacturer must submit to FDA a report that demonstrates that the tobacco product is modified within the meaning of section 905(j)(3), the modifications are to a product that is commercially marketed and in compliance with the requirements of the FD&C Act, and all of the modifications are covered by exemptions granted by the Secretary pursuant to section 905(j)(3). FDA estimated the total hours for exemptions from Substantial Equivalence Requirements would be 9,363 hours.

FDA's estimates are based on full analysis of economic impacts (Ref. 204) and information gathered from other FDA-regulated products.

4. Reports Intended To Demonstrate the Substantial Equivalence of a New Tobacco Product (OMB Control Number 0910–0673)

Description of Respondents: Respondents to this collection of information are manufacturers of deemed tobacco products who seek to submit a report to FDA demonstrating that a tobacco product is substantially equivalent to a valid predicate product under section 905(j)(1)(A)(i) of the FD&C Act.

Section 905(j)(1) of the FD&C Act authorizes FDA to establish the form and manner of the submission. FDA issued guidance intended to assist persons submitting reports under section 905(j) of the FD&C Act and to explain, among other things, FDA's interpretation of the statutory sections related to SE (see the Guidance for Industry and FDA Staff entitled "Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products" (76 FR 789, January 6, 2011)).

Under the recently issued guidance, which published in the **Federal Register** of September 8, 2015, entitled, "Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions" (Edition 2), FDA is recommending that certain modifications might be addressed in either a "Same Characteristics SE Report" or "Product Quantity Change Report." In some circumstances manufacturers may be able to submit a shorter SE report. In particular, if a tobacco product is distinct (*e.g.*, it has a different name), but has the same characteristics as a valid predicate product, manufacturers may submit a Same Characteristics SE Report. If the only change to the tobacco product is a change to product quantity, and the per-weight composition inside the package remains identical, the manufacturer may submit a Product Quantity Change SE Report. FDA's CTP estimates that it will take less time to prepare those shorter SE reports.

When groups of full or product quantity change SE reports have identical content, they may be bundled; when a group of similar reports are bundled, the subsequent bundled reports are expected to take less time to prepare than the initial report.

FDA recognizes that many manufacturers of newly deemed products may be at the inception of their businesses. Therefore, FDA is announcing that the Agency may grant extension requests made by small-scale tobacco product manufacturers for SE Reports that need additional time to respond to deficiency letters for the first 30 months following the effective date of this rule.

FDA estimates the additional annual burden for the information collection as a result of this rule as follows:

TABLE 10—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent [2]	Total annual responses	Average burden per response (in hours)	Total hours
Full SE Initial Sections 905(j)(1)(A)(i) and 910(a) and § 25.40 Environmental Assessments:					
Cigar Manufacturers (Including Large, Small, and Importers)	168	1	168	300	50,400
Pipe and Waterpipe Tobacco Manufacturers (Including Importers)	151	1	151	300	45,300
Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers (ENDS and Delivery Systems (Including Importers))	16	1	16	300	4,800
Total Hours (sections 905(j)(1)(A)(i) and 910(a))					100,500
Full SE Bundled 905(j)(1)(A)(i) and 910(a) and § 25.40 Environmental Assessments:					
Cigar Manufacturers (Including Large, Small, and Importers)	151	1	151	90	13,590
Pipe and Water Tobacco Manufacturers (Including Importers)	83	1	83	90	7,470
Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers (ENDS and Delivery Systems (Including Importers))	16	1	16	90	1,440
Total Hours					22,500
Same Characteristics SE Report and § 25.40 Environmental Assessments:					
Cigar Manufacturers (Including Large, Small, and Importers)	285	1	285	47	13,395
Pipe and Waterpipe Tobacco Manufacturers (Including Importers)	132	1	132	47	6,204
Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers (ENDS and Delivery systems (Including Importers))	1	1	1	47	47

TABLE 10—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Activity	Number of respondents	Number of responses per respondent [2]	Total annual responses	Average burden per response (in hours)	Total hours
Total Same Characteristics					19,646
Product Quantity Change Initial and § 25.40 Environmental Assessments:					
Cigar Manufacturers (Including Large, Small, and Importers)	108	1	108	87	9,396
Pipe and Waterpipe Tobacco Manufacturers (Including Importers)	30	1	30	87	2,610
Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers (ENDS and Delivery systems (Including Importers))	1	1	1	87	87
Total Product Quantity Change Initial					12,093
Product Quantity Change Bundled and § 25.40 Environmental Assessments:					
Cigar Manufacturers (Including Large, Small, and Importers)	42	1	42	62	2,604
Pipe and Waterpipe Tobacco Manufacturers (Including Importers)	12	1	12	62	744
Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers (ENDS and Delivery systems (Including Importers))	1	1	1	62	62
Total Product Quantity Change					3,410
Total Hours ("Reports Intended to Demonstrate the Substantial Equivalence of a New Tobacco Product")					158,149

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

[2] This number is estimated to be the total annual responses divided by the number of respondents, rounded to the nearest hundredth.

FDA has based these estimates on the full analysis of economic impacts (Ref. 204) and experience with the existing information collection that applies to tobacco products currently subject to the FD&C Act (*i.e.*, cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco). In addition, anyone submitting an SE report is required to submit an environmental assessment under § 25.40.

The burden for environmental reports has been included in the burden per response for each type of SE report.

FDA estimates that 335 respondents will prepare and submit 335 section 905(j)(1)(A)(i) Full SE Initial reports each year and that it will take a manufacturer approximately 300 hours per report to prepare the reports of SE and environmental assessment for a new tobacco product.

FDA estimates that we will receive 335 Full SE Initial reports for a total of 100,500 hours. We estimate 250 Full SE Bundled Reports for a total of 22,500 hours. FDA estimates that we will receive 418 Same Characteristics SE Reports for a total of 19,646 hours. FDA estimates receiving 139 Initial Product Quantity Change reports for a total of 12,093 hours. We estimate receiving 55 Product Quantity Change Bundled SE reports for a total of 3,410 hours. Based on FDA's experience with environmental assessments (EAs) for currently regulated tobacco products, we expect industry to spend 80 hours to prepare an environmental assessment for a full SE Report, but less time to prepare an environmental assessment for shorter SE reports.

Therefore, FDA estimates the burden for submission of SE information will be 158,149 hours.

5. Electronic Importer's Entry Notice (OMB Control Number 0910–0046)

Description of Respondents: Respondents to this collection of information are importers of tobacco products being imported or offered for import into the United States whose products meet the same requirements of the Tobacco Control Act as domestic tobacco products.

With the passage of the Tobacco Control Act, section 801 of the FD&C Act (21 U.S.C. 381) was amended to add tobacco products to the inventory of FDA-regulated products. The revised section 801 charges the Secretary of Health and Human Services, through FDA, with the responsibility of assuring that foreign-origin, FDA-regulated foods, drugs, cosmetics, medical devices, radiological health, and tobacco products being imported or offered for import into the United States meet the same requirements of the FD&C Act as domestic products and for preventing products from entering the country if they are not in compliance. The discharge of this responsibility involves close coordination and cooperation between FDA headquarters and field inspectional personnel and the U.S. Customs and Border Protection (CBP). This collection of information is being used by FDA to review and prevent imported products from entering the United States if the products do not meet the same requirements of the FD&C Act as do domestic products.

Until October 1995, importers were required to file manual entry on OMB-approved forms, which were accompanied by related documents. Information provided by these forms included information such as country of origin, name of the importing vessel, entry number (assigned by CBP), port of entry, the port of lading and unlading, value in U.S. dollars, shipper or manufacturer, importer of record, original consignee, broker, broker's reference number and CBP house box number, bill of lading numbers, and location of goods. FDA stopped using these paper forms effective October 1, 1995, to eliminate duplication of information and to reduce the paperwork burden both on the import community and FDA. The Agency then developed and implemented an automated nationwide entry processing system, which enabled FDA to more efficiently obtain and process the information it requires to fulfill its regulatory responsibility.

Most of the information FDA requires to carry out its regulatory responsibilities under section 801 of the FD&C Act is already provided electronically by filers to CBP. Because CBP relays this data to FDA using an electronic interface, the majority of data submitted by the entry filer need be done only once.

FDA estimates the additional annual burden for the information collection as a result of this rule as follows:

TABLE 11—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Importers of Cigars who are Considered Manufacturers.	216	159	34,344	0.14 (8½ minutes)	4,808
Importers of Pipe and Waterpipe Tobacco Who Are Considered Manufacturers.	43	123	5,289	0.14 (8½ minutes)	740
Importers Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers (ENDS).	14	68	952	0.14 (8½ minutes)	133
Total Hours Importation of Tobacco Products	....	....	....	....	5,681

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA estimates the burden hours to be 5,681 burden hours (4,808 + 740 + 133 hours). This reflects the addition of the newly deemed tobacco products to the list of FDA's regulated products. When testing the use of electronic and paper forms, FDA determined that the average time for completing either electronic or manual entries was the same.

Based on the original data collected by FDA when the importer entry notice information collection was most recently approved, it is expected that each respondent will take 0.14 hour (8½ minutes) to respond. The estimated hours per response are expected to remain the same for tobacco importers.

FDA estimates that there will be no additional costs to provide import data electronically to FDA, as filers already have equipment and software in place to enable them to provide data to CBP via the automated system. Therefore, no additional software or hardware need be developed or purchased to enable filers to file the FDA data elements at the same time they file entries electronically with CBP.

6. Exports: Notification and Recordkeeping Requirements (OMB Control Number 0910–0482)

Description of Respondents: Respondents are manufacturers, distributors, and other persons who export tobacco products not intended for sale in the United States.

In a rule published on February 2, 2012 (77 FR 5171), FDA amended certain of its general regulations to include tobacco products, where appropriate, in light of FDA's authority to regulate these products under the Tobacco Control Act (conforming amendments rule). The conforming amendments rule subjects tobacco products to the same general requirements that apply to other FDA-regulated products, where appropriate. The conforming amendments rule amended 21 CFR 1.101(b), among other sections, to require persons who export human drugs, biologics, devices, animal drugs, foods, cosmetics, and tobacco products that may not be sold in the United States to maintain records demonstrating their compliance with the requirements in section 801(e)(1) of the FD&C Act. Section 801(e)(1) requires exporters to keep records demonstrating that the exported product: (1) Meets with the foreign purchaser's specifications; (2) does not conflict with the laws of the foreign country; (3) is labeled on the outside of the shipping package that is intended for export; and (4) is not sold or offered for sale in the United States. These criteria also could be met by maintaining other documentation, such as letters from a foreign government agency or notarized certifications from a responsible company official in the United States stating that the exported product does not conflict with the laws of the foreign country.

FDA estimates the annual burden for the information collection as a result of this rule as follows:

TABLE 12—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1] [2]

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (in hours)	Total hours
21 CFR 1.101(b):					
Cigar Manufacturers (Large and Small)	57	3	171	22	3,762
Pipe and Waterpipe Tobacco Manufacturers	37	3	111	22	2,442
Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers (ENDS) ..	93	3	279	22	6,138

TABLE 12—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1] [2]—Continued

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (in hours)	Total hours
Exports: Notification and Recordkeeping Requirements					12,342

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

[2] At publication of the NPRM, the burden for these activities were under OMB control number 0910–0690. The burden has since been transferred to OMB control number 0910–0482.

The Agency has estimated the number of respondents and burden hours associated with the recordkeeping requirements by reviewing Agency records and using Agency expert resources who have experience and information regarding tobacco product exporters. FDA estimates that 187 establishments (50 percent of all the tobacco manufacturers listed in the collection of information under OMB Control Number 0910–0046 in this document who manufacture cigars, pipe tobacco, waterpipe, other tobacco products, and ENDS) could be involved in the exporting of all tobacco products annually. Based on previous recordkeeping estimates for the exporter's reporting burden in the existing OMB-approved collection of information (OMB Control Number 0910–0482, "Export Notification and Recordkeeping Requirements"), each establishment will maintain an average of three records per year, and it will take each recordkeeper an average of 22 hours per recordkeeper to maintain each record. The Agency estimates 12,342 burden hours will be needed for tobacco product exporters to create and maintain records demonstrating compliance with section 801(e)(1) of the FD&C Act.

7. Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007 (OMB Control Number 0910–0775)

Description of Respondents: Respondents to this collection of information are manufacturers of tobacco products who wish to demonstrate that their tobacco product was commercially marketed in the United States on February 15, 2007, and is a grandfathered product not subject to premarket review.

On September 29, 2014, FDA published the guidance document entitled "Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007". This guidance provides information on how a manufacturer may demonstrate that a tobacco product was commercially marketed in the United States on February 15, 2007, and is, therefore, a grandfathered product not subject to premarket review. The guidance recommends that the manufacturer provide evidence that may include, among other things, dated copies of advertisements, dated catalog pages, dated promotional material, and dated bills of lading. FDA recommends that the manufacturer submit adequate information to demonstrate that the tobacco product was commercially marketed in the United States on February 15, 2007.

The estimate for the number of hours in the existing collection is FDA's estimate of how long it might take one to review, gather, and submit dated information if making a request for an Agency determination.

FDA estimates the annual burden for the information collection as a result of this rule as follows:

TABLE 13—ESTIMATED ANNUAL REPORTING BURDEN[1] [2]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Cigar Manufacturers (including large and small cigars and importers)	1	1	1	5	5
Pipe Tobacco Manufacturers (Including Importers)	1	1	1	5	5
Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers (Including Importers)	1	1	1	5	5
Total Hours Establishing that a Tobacco Product was Commercially Marketed in the United States as of February 15, 2007					15

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

[2] At publication of the NPRM, this collection was not yet approved by OMB. On September 8, 2014, OMB approved the information collection for 3 years.

Based on FDA's experiences to date, and given that stand-alone grandfather submissions are purely voluntary, FDA does not anticipate that many manufacturers will make such submissions, but this option is available. As such, we assigned one respondent annually per type of product FDA estimates it will take a manufacturer approximately 5 hours to complete and submit for FDA review the evidence required by this collection of information for a total of 15 hours.

C. Burdens Associated With Tobacco Products Currently Subject to the FD&C Act But Not Yet Approved by OMB

The information collections described in this section also involve collections that have been previously made available for public comment because they involved tobacco products currently subject to chapter IX of the FD&C Act. However, these information collections have not yet been approved by OMB.

FDA based the estimates on the existing collections that were previously made available for comment.

- Applications for Premarket Review of New Tobacco Products

Description of Respondents: The respondents to this collection of information are manufacturers who seek a marketing authorization order under section 910(c)(1)(A)(i) of the FD&C Act.

On September 28, 2011, FDA announced the availability of a draft guidance entitled "Applications for Premarket Review of New Tobacco Products". This guidance, when finalized, will represent the Agency's current thinking on the topic. Section 910(a)(1) of the FD&C Act defines a "new tobacco product" as a tobacco product that was not commercially marketed in the United States on February 15, 2007, or modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007. An order under section 910(c)(1)(A)(i) of the FD&C Act is required prior to marketing a new tobacco product. This requirement applies unless the product has been shown to be substantially equivalent to a valid predicate product or is exempt from SE.

Section 910(b) of the FD&C Act states that a PMTA shall contain full reports of all investigations of health risks; a full statement of all components, ingredients, additives, and properties, and of the principle or principles of operation of such tobacco product; a full description of methods of manufacturing and processing (which includes; a listing of all manufacturing, packaging, and control sites for the product); an explanation of how the product complies with applicable tobacco product standards; samples of the product and its components; and labeling.

FDA also encourages persons who would like to study their new tobacco product to meet with the OS in CTP to discuss their investigational plan. The request for a meeting should be sent in writing to the Director of CTP's OS and should include adequate information for FDA to assess the potential utility of the meeting and to identify FDA staff necessary to discuss agenda items. FDA is required to deny a PMTA and issue an order that the product may not be introduced or delivered for introduction into interstate commerce under section 910(c)(1)(A)(ii) of the FD&C Act if FDA finds that:

- The manufacturer has not shown that the product is appropriate for the protection of the public health,
- the manufacturing, processing, or packing methods, facilities, or controls do not conform to good manufacturing practices issued under section 906(e) of the FD&C Act,
- the labeling is false or misleading in any particular, or
- the manufacturer has not shown that the product complies with any tobacco product standard in effect under section 907 of the FD&C Act.

FDA estimates the annual burden for the information collection as a result of this rule as follows:

TABLE 14—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Obtaining an FDA Order Authorizing Marketing of Tobacco Product (the application) and § 25.40 Environmental Assessments:					
Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers (ENDS Liquids and ENDS Delivery Systems (Including Importers))	200	3.75	750	1,713	1,284,750
Total Hours Obtaining an FDA Order Authorizing Marketing of Tobacco Product (the application)					1,284,750
Request for Meeting with CTP's Office of Science to Discuss Investigational Plan:					
Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers (ENDS Liquids and ENDS Delivery Systems (Including Importers))	200	1	200	4	800
Total Hours Request for Meeting with CTP's Office of Science to Discuss Investigational Plan					800
Total Hours "Applications for Premarket Review of New Tobacco Products"					1,285,550

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA estimates that it will take each respondent approximately 1,500 hours to prepare a PMTA seeking an order from FDA allowing the marketing of a new tobacco product. FDA also estimates that it would on average take an additional 213 hours to prepare an environmental assessment in accordance with the requirements of § 25.40, for a total of 1,713 hours per PMTA application. This average represents a wide range of hours that will be required for these applications under different circumstances, with some requiring more hours (*e.g.*, as many as 5,000 hours for early applications that involve complex products and for which the company has no experience conducting studies or preparing analysis of public health impacts, or for which reliance on master files is not possible) as well as many requiring fewer hours (*e.g.*, as few as 50 hours for applications for products that are very similar to other new products).

Although FDA has decreased the burden per each PMTA, we have increased the number of expected responses for ENDS manufacturers. We attribute this increase to the rapid growing ENDS market since the NPRM was published. FDA's estimate includes anticipated burden for the writing of an application, including intracompany edits and approvals. FDA also estimates the number of PMTAs that FDA expects to receive annually will be 750 (642 ENDS Liquids and 108 ENDS Delivery Systems).

We are clarifying here that a PMTA may require one or more types of studies including chemical analysis, nonclinical studies, and clinical studies. FDA expects that chemical and design parameter analysis would include the testing of applicable HPHCs and nonclinical analysis would include literature synthesis and, as appropriate, some combination of in vitro or in vivo studies, and computational analyses. For the clinical study component, one or more types of studies may be included to address, as needed, perception, use pattern, or health impact. It is possible that an applicant may not need to conduct any new nonclinical or clinical studies. We note that for most applications, FDA does not expect that applicants will include randomized clinical trials, like those conducted to support drug and device approvals.

For tobacco products already on the market at the time of the final rule, much of the information required to support a PMTA may be obtained from previously published research on similar products. Therefore, FDA expects that a large portion of applications may be reviewed with no or minimal new nonclinical or clinical studies being conducted to support an application. In contrast, nonclinical and clinical studies may be required for market authorization of a new product for which there is limited understanding of its potential impact on the public health. The range of hours involved to compile these two types of applications would be quite variable.

FDA anticipates that the 200 potential respondents to this collection may need to meet with CTP's Office of Science to discuss their investigational plans. To request this meeting, applicants should compile and submit information to FDA for meeting approval. FDA estimates that it will take approximately 4 hours to compile this information, for a total of 800 hours additional burden (200 respondents × 4 hours).

Therefore, the total annual burden for submitting PMTA applications is estimated to be 1,285,550 hours. FDA's estimates are based on the corresponding information collection estimates that apply to tobacco products currently subject to the FD&C Act and an assumption that manufacturers would submit applications for the premarket review of tobacco products.

D. New Collections of Information That Apply Only to Deemed Tobacco Products

1. Exemption From the Required Warning Statement Requirement

Description of Respondents: Respondents are manufacturers who, to obtain an exemption from the required addictiveness warning, certify to FDA that their product does not contain nicotine and that the manufacturer has data to support that assertion.

This rule contains a new information collection that pertains to an exemption process related to the requirement to include the warning statement in § 1143.3(a)(1). Section1143.3(c) will provide an exemption to the manufacturer of a product that otherwise would be required to include the warning statement in § 1143.3(a)(1) on its packages and in its advertisements, *i.e.,* "WARNING: This product contains nicotine. Nicotine is an addictive chemical." This warning will be required to appear on at least 30 percent of the two principal display panels of the package and on at least 20 percent of the area of the advertisement.

To obtain an exemption from this requirement, a manufacturer would be required to certify to FDA that its product does not contain nicotine and that the manufacturer has data to support that assertion. For any product that obtains this exemption, the section requires that the product bear the statement: "This product is made from tobacco." The parties that package and label such products will share responsibility for ensuring that this alternative statement is included on product packages and in advertisements. The rule will permit companies to obtain an exemption from this warning requirement in the event that such tobacco products are developed in the future.

FDA estimates the annual burden for the information collection as a result of this rule as follows:

TABLE 15—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Certification Statement	1	1	1	20	20
Total Exemptions From the Required Warning Statement Requirement					20

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimated average burden per response is based on information collection estimates that apply to tobacco products currently subject to the FD&C Act. Although very few certifications are expected for tobacco products that do not contain nicotine, FDA estimates that the number of certification submissions could rise if the Agency decides in the future to address not only nicotine, but any other addictive substances.

The estimated hours listed in the burden table for certification submissions reflect the time needed to test the product for nicotine and to prepare and submit the self-certification request. FDA expects that these types of certifications will be very rare and estimates that the Agency will receive on average one submission per year.

FDA concludes that the labeling statements in §§ 1143.3(a)(1) and 1143.5(a)(1) and the alternative statement in § 1143.3(c) (*i.e.,* "This product is made from tobacco") are not subject to review by OMB because they do not constitute a "collection of information" under the PRA (44 U.S.C. 3501–3520). Rather, these labeling statements are a "public disclosure" of information originally supplied by the Federal Government to the recipient for the purpose of "disclosure to the public" (5 CFR 1320.3(c)(2)).

2. Submitting Warning Plans for Cigar Manufacturers, Importers, Distributors, and Retailers

Description of Respondents: The respondents to this collection of information are manufacturers, importers, distributors, and retailers of cigar products who will be required to submit warning plans for cigars to FDA.

The requirement for submission of warning plans for cigar products, and the specific requirements relating to the random display and distribution of required warning statements on cigar packaging and quarterly rotation of required warning statements in alternating sequence on cigar product advertising, appear in § 1143.5(c).

The six warnings for cigars (five specifically for cigars and the one addictiveness warning) will be required to be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of cigar sold in product packaging and be randomly distributed in all areas of the United States in which the product is marketed accordance with a warning plan submitted to and approved by FDA. For advertisements, the warning statements must be rotated quarterly in alternating sequence in each advertisement for each brand of cigar in accordance with a warning plan submitted to and approved by FDA.

For cigar products that are on the market as of the publication date of the final rule, the effective date for the requirement to submit warning plans by responsible manufacturers, distributors, importers, and retailers is 1 year after the date of publication of the final rule. FDA is establishing this effective date 1 year before the effective date of the remainder of the part 1143 requirements because the Agency anticipates that there will be a need for considerable communication with submitters during its review of the warning plan submissions. FDA will work with the submitters to ensure that the plans submitted meet the established criteria for approval under part 1143. FDA also intends to update the warning plan draft guidance and information collection, which currently pertains to smokeless tobacco products, to assist manufacturers, importers, distributors, and retailers of cigars with the submission of warning plans. The information collection in this draft guidance is approved under OMB Control Number 0910–0671. The draft guidance document discusses, among other things: The statutory requirement to submit a warning plan; definitions; who submits a warning plan; the scope of a warning plan; when to submit a warning plan; what information should be submitted in a warning plan; where to submit a warning plan; and what approval of a warning plan means.

The warning statements on cigar packaging must be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of cigar sold and are required to be randomly distributed in all areas of the United States in which the product is marketed in accordance with a warning plan submitted by the responsible cigar manufacturer, importer, distributor, or retailer to and approved by FDA.

To clarify, retailers of cigars sold individually and not in product packaging are not required to submit a warning plan for warnings on packages, because the warning signs posted at a retailer's point-of-sale would include all six warnings applicable to cigars, as we have noted in § 1143.5(c)(1). Therefore, it is not necessary to submit a rotational warning plan for them. However, manufacturers, distributors, and those retailers who are responsible for or direct the health warning of the advertisements of such products must submit a warning plan for their advertisements for FDA approval. The rule requires them to include warnings on advertisements, and the warnings that must be rotated quarterly in alternating sequence in each advertisement for each brand of cigar, in accordance with an FDA approved warning plan.

FDA is also requiring that the required warning statements be rotated quarterly in alternating sequence in each advertisement for each brand of cigar, regardless of whether the cigar is sold in product packaging. This rotation of warning statements in cigar advertisements also must be done in accordance with a warning plan submitted by the responsible cigar manufacturer, importer, distributor, or retailer to and approved by FDA.

FDA estimates the annual burden for the information collection as a result of this rule as follows:

TABLE 16—ESTIMATED ANNUAL REPORTING BURDEN [1]

Cigar warning plan	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Manufacturers, Importers, and Retailers	329	1	329	120	39,480
Total Cigar Warning Plan					39,480

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden estimates are based on FDA's experience with smokeless warning plans and the associated information collection (OMB Control Number 0910–0671) as well as warning plans for cigarettes submitted to the FTC prior to the implementation of the Tobacco Control Act on June 22, 2009.

We estimate 329 entities will submit warning plans, and it will take an average of 120 hours per respondent to prepare and submit a warning plan for packaging and advertising for a total of 39,480 hours.

3. Small-Scale Manufacturer Report

Description of Respondents: The respondents to this collection of information are manufacturers known as "small-scale tobacco product manufacturers."

As discussed in section IV, FDA requested comment on the ability of smaller manufacturers of newly deemed tobacco products to fully comply with the requirements of the FD&C Act and how FDA might be able to address those concerns. Considering the comments and FDA's finite enforcement resources, the Agency's view is that those resources may not be best used in immediately enforcing the provisions of this rule against certain manufacturers that are small-scale tobacco product manufacturers and that fail to comply with certain requirements of the FD&C Act. FDA retains discretion in all cases to conduct an individualized inquiry and to consider any and all relevant facts in determining whether to bring an enforcement action.

Generally, FDA considers a "small-scale tobacco product manufacturer" to be a manufacturer of any regulated tobacco product that employs 150 or fewer full-time equivalent employees and has annual total revenues of $5,000,000 or less. FDA considers a manufacturer to include each entity that it controls, is controlled by, or is under common control with such manufacturer. To help make FDA's individual enforcement decisions more efficient, a manufacturer may voluntarily submit information regarding employment and revenues. FDA does not believe a large number of manufacturers who fit the criteria of a small-scale tobacco product manufacturer would submit the voluntary information.

FDA estimates that there are approximately 75 small-scale manufacturers who will voluntarily submit information. FDA believes it will take respondents 2 hours to voluntarily submit information regarding employment and revenues for a total of 150 hours.

FDA has estimated the burden for submitting the "small-scale tobacco product manufacturer" annual report as follows:

TABLE 17—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Small-Scale Manufacturer Reporting	75	1	75	2	150
Total Small-Scale Manufacturer Report					150

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The total burden for these new collections of information in this rulemaking is 1,621,212 reporting hours (121,604 + 1,200 + 9,363 + 158,149 + 5,681 + 15 + 1,285,550 + 20 + 39,480 + 150) and 12,342 recordkeeping hours for a total of 1,633,554 burden hours.

The information collection provisions in this final rule have been submitted to OMB for review as required by section 3507(d) of the Paperwork Reduction Act of 1995.

Before the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

XX. Executive Order 13132; Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

XXI. Executive Order 13175; Tribal Consultation

In accordance with Executive Order 13175, FDA has consulted with Tribal Government officials. FDA sought comment from Tribal Governments on April 25, 2014, and conducted a consultation with tribes via Webinar regarding the NPRM on May 29, 2014. FDA received one comment from a tribe stating that FDA failed to ensure meaningful and timely input from tribal officials as required by Executive Order 13175 and requesting tribal consultation in relation to existing premarket review activities for cigarettes, roll-your-own tobacco, and smokeless tobacco. In response, FDA conducted a face-to-face meeting with the tribe regarding the NPRM on January 21, 2015. FDA has determined that this final rule does not have tribal implications under Executive Order 13175, because it does not, to our knowledge, have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, nor does it impose substantial direct compliance costs.

(Comment 305) One comment stated that FDA failed to ensure meaningful and timely input from tribal officials as required by Executive Order 13175 and the HHS Consultation Policy. The comment acknowledged FDA's "Dear Tribal Leader" letter and Webinar and requested a face-to-face meeting between FDA and its tribe in relation to existing premarket review activities for cigarettes, roll-your-own tobacco, and smokeless tobacco.

(Response) FDA adheres to Executive Order 13175 and the HHS Consultation Policy. FDA is committed to meaningful consultation with federally recognized tribes on FDA's implementation and enforcement of the Tobacco Control Act. As a result of the tribe's inquiry, FDA participated in a face-to-face meeting.

(Comment 306) One comment encouraged FDA to respect tribal sovereignty in its enforcement of the tobacco regulation. The comment recommended that FDA provide both training and funding opportunities to tribal governments to alleviate the economic burdens stemming from enforcement of the rule. The comment urged FDA to make certain the regulatory burdens do not limit the economic viability of tribal operations.

(Response) FDA recognizes tribal sovereignty and tribal self-regulation and will work in partnership with tribal leaders to monitor compliance with this rule. As explained in this rule, FDA is implementing this rule to protect public health. However, FDA recognizes that compliance with many of the automatic provisions may be challenging at first for entities that are new to Federal public health regulation and as a result, provided compliance policies relating to provisions such as premarket authorizations and provided additional time to comply with certain requirements of the FD&C Act for small-scale tobacco manufacturers. FDA will provide training and other opportunities to tribal governments after the rule is finalized.

XXII. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m. Monday through Friday; they are also available electronically at *http://www.regulations.gov*. FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

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278. Environmental Assessment for Regulations (21 CFR 1100, 1140, and 1143) to deem tobacco products meeting the statutory definition of "tobacco product" to be subject to the Federal Food, Drug, and Cosmetic Act, to revise existing regulations to include

restrictions on the sale and distribution of covered tobacco products, and to require the use of health warning statements for cigarette tobacco, roll-your-own tobacco, and covered tobacco products.

279. Finding of No Significant Impact for Regulations (21 CFR 1100, 1140, and 1143) to deem tobacco products meeting the statutory definition of "tobacco product" to be subject to the Federal Food, Drug, and Cosmetic Act, to revise existing regulations to include restrictions on the sale and distribution of covered tobacco products, and to require the use of health warning statements for cigarette tobacco, roll-your-own tobacco, and covered tobacco products.

List of Subjects

21 CFR Part 1100

Smoking, Tobacco.

21 CFR Part 1140

Advertising, Labeling, Smoking, Tobacco.

21 CFR Part 1143

Advertising, Labeling, Packaging and containers, Smoking, Tobacco.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR chapter I is amended as follows:

■ 1. Add part 1100 to subchapter K to read as follows:

PART 1100—TOBACCO PRODUCTS SUBJECT TO FDA AUTHORITY

Sec.
1100.1 Scope.
1100.2 Requirements.
1100.3 Definitions.

Authority: 21 U.S.C. 387a(b), 387f(d) and Pub. L. 111–31.

§ 1100.1 Scope.

In addition to FDA's authority over cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco, FDA deems all other products meeting the definition of *tobacco product* under section 201(rr) of the Federal Food, Drug, and Cosmetic Act, except accessories of such other tobacco products, to be subject to the Federal Food, Drug, and Cosmetic Act.

§ 1100.2 Requirements.

Cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco are subject to chapter IX of the Federal Food, Drug, and Cosmetic Act and its implementing regulations. FDA has deemed all other tobacco products, except accessories of such other tobacco products, subject to chapter IX of the Federal Food, Drug, and Cosmetic Act and its implementing regulations.

§ 1100.3 Definitions.

For the purposes of this part:

Accessory means any product that is intended or reasonably expected to be used with or for the human consumption of a tobacco product; does not contain tobacco and is not made or derived from tobacco; and meets either of the following:

(1) Is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product; or

(2) Is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a tobacco product but

(i) Solely controls moisture and/or temperature of a stored tobacco product; or

(ii) Solely provides an external heat source to initiate but not maintain combustion of a tobacco product.

Component or *part* means any software or assembly of materials intended or reasonably expected:

(1) To alter or affect the tobacco product's performance, composition, constituents, or characteristics; or

(2) To be used with or for the human consumption of a tobacco product. Component or part excludes anything that is an accessory of a tobacco product.

Package or *packaging* means a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane), in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers.

Tobacco product. As stated in section 201(rr) of the Federal Food, Drug, and Cosmetic Act in relevant part, a tobacco product:

(1) Means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product); and

(2) Does not mean an article that is a drug under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act, a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act, or a combination product described in section 503(g) of the Federal Food, Drug, and Cosmetic Act.

PART 1140—CIGARETTES, SMOKELESS TOBACCO, AND COVERED TOBACCO PRODUCTS

■ 2. The authority citation for 21 CFR part 1140 continues to read as follows:

Authority: 21 U.S.C. 301 *et seq.*, Sec. 102, Pub. L. 111–31, 123 Stat. 1776.

■ 3. Revise the heading to part 1140 as set forth above.

■ 4. Revise § 1140.1 to read as follows:

§ 1140.1 Scope.

(a) This part sets out the restrictions under the Federal Food, Drug, and Cosmetic Act on the sale, distribution, and use of cigarettes, smokeless tobacco, and covered tobacco products. Section 1140.16(d) sets out restrictions on the distribution of free samples for cigarettes, smokeless tobacco, and other tobacco products (as such term is defined in section 201 of the Federal Food, Drug, and Cosmetic Act).

(b) The failure to comply with any applicable provision in this part in the sale, distribution, and use of cigarettes, smokeless tobacco, covered tobacco products, or other tobacco products renders the product misbranded under the Federal Food, Drug, and Cosmetic Act.

(c) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

■ 5. Revise § 1140.2 to read as follows:

§ 1140.2 Purpose.

The purpose of this part is to establish restrictions on the sale, distribution, and use of cigarettes, smokeless tobacco, and covered tobacco products in order to reduce the number of children and adolescents who use these products, and to reduce the life-threatening consequences associated with tobacco use.

■ 6. Revise § 1140.3 to read as follows:

§ 1140.3 Definitions.

For the purposes of this part:

Accessory means any product that is intended or reasonably expected to be used with or for the human consumption of a tobacco product; does not contain tobacco and is not made or derived from tobacco; and meets either of the following:

(1) Is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product; or

(2) Is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a tobacco product but

(i) Solely controls moisture and/or temperature of a stored product; or

(ii) Solely provides an external heat source to initiate but not maintain combustion of a tobacco product.

Cigarette. (1) Means a product that:

(i) Is a tobacco product and

(ii) Meets the definition of the term "cigarette" in section 3(1) of the Federal Cigarette Labeling and Advertising Act; and

(2) Includes tobacco, in any form, that is functional in the product, which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette or as roll-your-own tobacco.

Cigarette tobacco means any product that consists of loose tobacco that is intended for use by consumers in a cigarette. Unless otherwise stated, the requirements applicable to cigarettes under this chapter also apply to cigarette tobacco.

Component or *part* means any software or assembly of materials intended or reasonably expected:

(1) To alter or affect the tobacco product's performance, composition, constituents, or characteristics; or

(2) To be used with or for the human consumption of a tobacco product. Component or part excludes anything that is an accessory of a tobacco product.

Covered tobacco product means any tobacco product deemed to be subject to the Federal Food, Drug, and Cosmetic Act under § 1100.2 of this chapter, but excludes any component or part that is not made or derived from tobacco.

Distributor means any person who furthers the distribution of a tobacco product, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption. Common carriers are not considered distributors for the purposes of this part.

Importer means any person who imports any tobacco product that is intended for sale or distribution to consumers in the United States.

Manufacturer means any person, including any repacker and/or relabeler, who manufactures, fabricates, assembles, processes, or labels a finished tobacco product.

Nicotine means the chemical substance named 3-(1-Methyl-2-pyrrolidinyl)pyridine or C[10]H[14]N[2], including any salt or complex of nicotine.

Package or *packaging* means a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane) in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers.

Point of sale means any location at which a consumer can purchase or otherwise obtain tobacco products for personal consumption.

Retailer means any person who sells tobacco products to individuals for personal consumption, or who operates a facility where vending machines or self-service displays are permitted under this part.

Roll-your-own tobacco means any tobacco product that, because of its appearance, type, packaging, or labeling, is suitable for use and likely to be offered to, or purchased by, consumers as tobacco for making cigarettes.

Smokeless tobacco means any tobacco product that consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral or nasal cavity.

Tobacco product. As stated in section 201(rr) of the Federal Food, Drug, and Cosmetic Act in relevant part, a tobacco product:

(1) Means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product) and

(2) Does not mean an article that is a drug under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act, a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act, or a combination product described in section 503(g) of the Federal Food, Drug, and Cosmetic Act.

■ 7. Revise § 1140.10 to read as follows:

§ 1140.10 General responsibilities of manufacturers, distributors, and retailers.

Each manufacturer, distributor, importer, and retailer is responsible for ensuring that the cigarettes, smokeless tobacco, or covered tobacco products it manufactures, labels, advertises, packages, distributes, imports, sells, or otherwise holds for sale comply with all applicable requirements under this part.

■ 8. Revise § 1140.14 to read as follows:

§ 1140.14 Additional responsibilities of retailers.

(a) In addition to the other requirements under this part, each cigarette and smokeless tobacco retailer is responsible for ensuring that all sales of cigarettes or smokeless tobacco to any person comply with the following requirements:

(1) No retailer may sell cigarettes or smokeless tobacco to any person younger than 18 years of age;

(2)(i) Except as otherwise provided in paragraph (a)(2)(ii) of this section and in § 1140.16(c)(2)(i), each retailer must verify by means of photographic identification containing the bearer's date of birth that no person purchasing the product is younger than 18 years of age;

(ii) No such verification is required for any person over the age of 26;

(3) Except as otherwise provided in § 1140.16(c)(2)(ii), a retailer may sell cigarettes or smokeless tobacco only in a direct, face-to-face exchange without the assistance of any electronic or mechanical device (such as a vending machine);

(4) No retailer may break or otherwise open any cigarette or smokeless tobacco package to sell or distribute individual cigarettes or a number of unpackaged cigarettes that is smaller than the quantity in the minimum cigarette package size defined in § 1140.16(b), or any quantity of cigarette tobacco or smokeless tobacco that is smaller than the smallest package distributed by the manufacturer for individual consumer use; and

(5) Each retailer must ensure that all self-service displays, advertising, labeling, and other items, that are located in the retailer's establishment and that do not comply with the requirements of this part, are removed or are brought into compliance with the requirements under this part.

(b) Notwithstanding the requirements in paragraph (a) of this section and in addition to the other requirements under this part, each retailer of covered tobacco products is responsible for ensuring that all sales of such covered tobacco products to any person comply with the following requirements:

(1) No retailer may sell covered tobacco products to any person younger than 18 years of age;

(2)(i) Except as otherwise provided in paragraph (a)(2)(ii) of this section and in § 1140.16(c)(2)(i), each retailer must verify by means of photographic identification containing the bearer's date of birth that no person purchasing the product is younger than 18 years of age;

(ii) No such verification is required for any person over the age of 26; and

(3) A retailer may not sell covered tobacco products with the assistance of any electronic or mechanical device (such as a vending machine), except in facilities where the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time.

■ 9. Add part 1143 to subchapter K to read as follows:

PART 1143—MINIMUM REQUIRED WARNING STATEMENTS

Sec.

1143.1 Definitions.
1143.3 Required warning statement regarding addictiveness of nicotine.
1143.5 Required warning statements for cigars.
1143.7 Language requirements for required warning statements.
1143.9 Irremovable or permanent required warning statements.
1143.11 Does not apply to foreign distribution.
1143.13 Effective date.

Authority: 21 U.S.C. 387a(b), 387f(d).

§ 1143.1 Definitions.

For purposes of this part:

Accessory means any product that is intended or reasonably expected to be used with or for the human consumption of a tobacco product; does not contain tobacco and is not made or derived from tobacco; and meets either of the following:

(1) Is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product; or

(2) Is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a tobacco product but

(i) Solely controls moisture and/or temperature of a stored tobacco product; or

(ii) Solely provides an external heat source to initiate but not maintain combustion of a tobacco product

Cigar means a tobacco product that:

(1) Is not a cigarette and

(2) Is a roll of tobacco wrapped in leaf tobacco or any substance containing tobacco.

Cigarette tobacco means any product that consists of loose tobacco that is intended for use by consumers in a cigarette. Unless otherwise stated, the requirements applicable to cigarettes under this chapter also apply to cigarette tobacco.

Component or *part* means any software or assembly of materials intended or reasonably expected:

(1) To alter or affect the tobacco product's performance, composition, constituents, or characteristics; or

(2) to be used with or for the human consumption of a tobacco product. Component or part excludes anything that is an accessory of a tobacco product.

Covered tobacco product means any tobacco product deemed to be subject to the Federal Food, Drug, and Cosmetic Act pursuant to § 1100.2 of this chapter, but excludes any component or part that is not made or derived from tobacco.

Package or *packaging* means a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane), in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers.

Principal display panels means the panels of a package that are most likely to be displayed, presented, shown, or examined by the consumer.

Point of sale means any location at which a consumer can purchase or otherwise obtain tobacco products for personal consumption.

Retailer means any person who sells tobacco products to individuals for personal consumption, or who operates a facility where vending machines or self-service displays are permitted under this part.

Required warning statement means a textual warning statement required to be on packaging and in advertisements for cigarette tobacco, roll-your-own tobacco, cigars, and other covered tobacco products.

Roll-your-own tobacco means any tobacco product that, because of its appearance, type, packaging, or labeling, is suitable for use and likely to be offered to, or purchased by, consumers as tobacco for making cigarettes.

Tobacco product. As stated in section 201(rr) of the Federal Food, Drug, and Cosmetic Act in relevant part, a tobacco product:

(1) Means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product) and

(2) Does not mean an article that is a drug under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act, a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act, or a combination product described in section 503(g) of the Federal Food, Drug, and Cosmetic Act.

§ 1143.3 Required warning statement regarding addictiveness of nicotine.

(a) *Packages.* (1) For cigarette tobacco, roll-your-own tobacco, and covered tobacco products other than cigars, it is unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States such product unless the tobacco product package bears the following required warning statement on the package label: "WARNING: This product contains nicotine. Nicotine is an addictive chemical."

(2) The required warning statement must appear directly on the package and must be clearly visible underneath any cellophane or other clear wrapping as follows:

(i) Be located in a conspicuous and prominent place on the two principal display panels of the package and the warning area must comprise at least 30 percent of each of the principal display panels;

(ii) Be printed in at least 12-point font size and ensures that the required warning statement occupies the greatest possible proportion of the warning area set aside for the required text;

(iii) Be printed in conspicuous and legible Helvetica bold or Arial bold type (or other sans serif fonts) and in black text on a white background or white text on a black background in a manner that contrasts by typography, layout, or color, with all other printed material on the package;

(iv) Be capitalized and punctuated as indicated in paragraph (a)(1) of this section; and

(v) Be centered in the warning area in which the text is required to be printed and positioned such that the text of the required warning statement and the other information on the principal display panel have the same orientation.

(3) A retailer of any tobacco product covered by paragraphs (a)(1) and (2) of this section will not be in violation of this section for packaging that:

(i) Contains a health warning;

(ii) Is supplied to the retailer by the tobacco product manufacturer, importer, or distributor, who has the required state, local, or Alcohol and Tobacco Tax and Trade Bureau (TTB)-issued license or permit, if applicable, and

(iii) Is not altered by the retailer in a way that is material to the requirements of this section.

(b) *Advertisements.* (1) For cigarette tobacco, roll-your-own tobacco, and covered tobacco products other than cigars, it is unlawful for any such tobacco product manufacturer, packager, importer, distributor, or retailer of the tobacco product to advertise or cause to be advertised within the United States any tobacco product unless each advertisement bears the required warning statement specified in paragraph (a)(1) of this section.

(2) For print advertisements and other advertisements with a visual component (including, for example, advertisements on signs, shelf-talkers, Internet Web pages, and electronic mail correspondence), the required warning statement must appear in the upper portion of the area of the advertisement within the trim area as follows:

(i) Occupy at least 20 percent of the area of the advertisement;

(ii) Appear in at least 12-point font size and ensures that the required warning statement occupies the greatest possible proportion of the warning area set aside for the required text;

(iii) Appear in conspicuous and legible Helvetica bold or Arial bold type (or other similar sans serif fonts) and in black text on a white background or white text on a black background in a manner that contrasts by typography, layout, or color, with all other material on the advertisement;

(iv) Be capitalized and punctuated as indicated in paragraph (a)(1) of this section;

(v) Be centered in the warning area in which the text is required to appear and positioned such that the text of the required warning statement and the other textual information in the advertisement have the same orientation; and

(vi) Be surrounded by a rectangular border that is the same color as the text of the required warning statement and that is not less than 3 millimeters (mm) or more than 4 mm.

(3) This paragraph (b) applies to a retailer only if that retailer is responsible for or directs the health warning required under the paragraph. However, this paragraph does not relieve a retailer of liability if the retailer displays, in a location open to the public, an advertisement that does not contain a health warning or contains a health warning that has been altered by the retailer in a way that is material to the requirements of this section.

(c) *Self-certification.* A tobacco product that would otherwise be required to bear the warning in paragraph (a)(1) of this section but does not contain nicotine is not required to bear the warning in paragraph (a)(1) of this section on packages or advertisements if the tobacco product manufacturer has submitted to FDA a confirmation statement certifying to be true and accurate that the product does not contain nicotine and that the tobacco product manufacturer has data to support that assertion. Any product not required to bear the warning in paragraph (a)(1) of this section must include the statement "This product is made from tobacco." on all packages and advertisements in accordance with the requirements of this part.

(d) *Small packages.* A tobacco product that would otherwise be required to bear the warning in paragraph (a)(1) of this section but is too small or otherwise unable to accommodate a label with sufficient space to bear such information is exempt from compliance with the requirement *provided* that the information and specifications required under paragraphs (a)(1) and (2) of this section appear on the carton or other outer container or wrapper if the carton, outer container, or wrapper has sufficient space to bear the information, or appear on a tag otherwise firmly and permanently affixed to the tobacco product package. In such cases, the carton, outer container, wrapper, or tag will serve as the location of the principal display panels.

§ 1143.5 Required warning statements for cigars.

(a) *Packages.* (1) It is unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any cigar product unless the product package bears one of the following required warning statements on the package label:

(i) WARNING: Cigar smoking can cause cancers of the mouth and throat, even if you do not inhale.

(ii) WARNING: Cigar smoking can cause lung cancer and heart disease.

(iii) WARNING: Cigars are not a safe alternative to cigarettes.

(iv) WARNING: Tobacco smoke increases the risk of lung cancer and heart disease, even in nonsmokers.

(v)(A) WARNING: Cigar use while pregnant can harm you and your baby.; or

(B) SURGEON GENERAL WARNING: Tobacco Use Increases the Risk of Infertility, Stillbirth and Low Birth Weight.

(vi) WARNING: This product contains nicotine. Nicotine is an addictive chemical.

(2) Each required warning statement must appear directly on the package and must be clearly visible underneath any cellophane or other clear wrapping as follows:

(i) Be located in a conspicuous and prominent place on the two principal display panels of the package and the warning area must comprise at least 30 percent of each of the principal display panels;

(ii) Appear in at least 12-point font size and ensure that the required warning statement occupies the greatest possible proportion of the warning area set aside for the required text;

(iii) Be printed in conspicuous and legible Helvetica bold or Arial bold type (or other similar sans serif fonts) and in black text on a white background or white text on a black background in a manner that contrasts by typography, layout, or color, with all other printed material on the package;

(iv) Be capitalized and punctuated as indicated in paragraph (a)(1) of this section; and

(v) Be centered in the warning area in which the text is required to be printed and positioned such that the text of the required warning statement and the other information on that principal display panel have the same orientation.

(3) No person may manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any cigar without a required warning statement, except for cigars that are sold individually and not in a product package. For cigars that are sold individually and not in a product package, the required warning statements must be posted at the retailer's point-of-sale in accordance with the following:

(i) All of the warnings in paragraph (a) of this section must be placed on a sign that is a minimum of 8.5 x 11 inches, posted on or within 3 inches of each cash register where payment may be made so that the sign(s) are unobstructed in their entirety and can be read easily by each consumer making a purchase;

(ii) The sign must be clear, legible, and conspicuous and be printed in black Helvetica bold or Arial bold type (or other similar sans serif fonts) against a solid white background in at least 17 point type with appropriate space between the warning statements;

(iii) Be printed in a manner that contrasts by typography, layout, or color, with all other printed material; and

(iv) Be capitalized and punctuated as indicated in paragraph (a)(1) of this section.

(4) A retailer of any cigar covered by paragraphs (a)(1) and (2) of this section will not be in violation of this section for packaging that:

(i) Contains a health warning;

(ii) Is supplied to the retailer by the tobacco product manufacturer, importer, or distributor who has the required state, local, or Alcohol and Tobacco Tax and Trade Bureau (TTB)-issued license or permit, if applicable, and

(iii) Is not altered by the retailer in a way that is material to the requirements of this section.

(b) *Advertisements.* (1) It is unlawful for any tobacco product manufacturer, packager, importer, distributor, or retailer of cigars to advertise or cause to be advertised within the United States any cigar unless each advertisement bears one of the required warning statements specified in paragraph (a)(1) of this section.

(2) For print advertisements and other advertisements with a visual component (including, for example, advertisements on signs, shelf-talkers, Internet Web pages, and electronic mail correspondence), each required warning statement must appear in the upper

portion of the area of the advertisement within the trim area as follows:

(i) Occupy at least 20 percent of the area of the advertisement;

(ii) Appear in at least 12-point font size that ensures that the required warning statement occupies the greatest possible proportion of the warning area set aside for the text required;

(iii) Appear in conspicuous and legible Helvetica bold or Arial bold type (or other similar sans serif fonts) and in black text on a white background or white text on a black background in a manner that contrasts by typography, layout, or color, with all other material on the advertisement;

(iv) Be capitalized and punctuated as indicated in paragraph (a)(1) of this section;

(v) Be centered in the warning area in which the text is required to appear and positioned such that the text of the required warning statement and the other textual information in the advertisement have the same orientation; and

(vi) Be surrounded by a rectangular border that is the same color as the text of the required warning statement and that is not less than 3 mm or more than 4 mm.

(3) This paragraph (b) applies to a retailer only if that retailer is responsible for or directs the warning statements required under the paragraph. However, this paragraph does not relieve a retailer of liability if the retailer displays, in a location open to the public, an advertisement that does not contain a health warning or contains a health warning that has been altered by the retailer in a way that is material to the requirements of this section.

(c) *Marketing requirements.* (1) Except for cigars sold individually and not in a product package, the warning statements required for packages in paragraph (a)(1) of this section must be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of cigar sold in product packaging and be randomly distributed in all areas of the United States in which the product is marketed in accordance with a plan submitted by the cigar manufacturer, importer, distributor, or retailer to, and approved by, the Food and Drug Administration.

(2) The warning statements required for advertisements in paragraph (a)(1) of this section must be rotated quarterly in alternating sequence in each advertisement for each brand of cigar in accordance with a plan submitted by the cigar manufacturer, importer, distributor, or retailer to, and approved by, the Food and Drug Administration.

(3) Each person required to randomly display and distribute or rotate warnings in accordance with an FDA-approved plan under this part shall submit a proposed warning plan to FDA no later than either 12 months after May 10, 2016, or 12 months before advertising or commercially marketing a product that is subject to such requirement, whichever is later.

§ 1143.7 Language requirements for required warning statements.

The text in each warning statement required in § 1143.3 or § 1143.5 must be in the English language, except as follows:

(a) In the case of an advertisement that appears in a non-English medium, the text in the required warning statement must appear in the predominant language of the medium whether or not the advertisement is in English, and;

(b) In the case of an advertisement that appears in an English language medium but that is not in English, the text in the required warning statement must appear in the same language as that principally used in the advertisement.

§ 1143.9 Irremovable or permanent required warning statements.

The warning statements required by this section must be indelibly printed on or permanently affixed to the package or advertisement. These warnings, for example, must not be printed or placed on a product label affixed to a clear outer wrapper that is likely to be removed to access the product within the package.

§ 1143.11 Does not apply to foreign distribution.

The provisions of this part do not apply to a manufacturer or distributor of tobacco products that does not manufacture, package, or import tobacco products for sale or distribution within the United States.

§ 1143.13 Effective date.

(a) Except as stated in paragraph (b) of this section, this part will take effect 24 months after May 10, 2016. The effective date will be with respect to the date of manufacture, provided that, in any case, beginning 30 days after the effective date, a manufacturer may not introduce into the domestic commerce of the United States any product, irrespective of the date of manufacture, that is not in conformance with this part.

(b) The requirement to submit a warning plan to FDA under § 1143.5(c)(3) will take effect 12 months after May 10, 2016.

Dated: May 3, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–10685 Filed 5–5–16; 8:45 am]

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FEDERAL REGISTER

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No. 90 May 10, 2016

Part IV

Office of Management and Budget

Statistical Policy Directive No. 2 Addendum: Standards and Guidelines for Cognitive Interviews; Notice

OFFICE OF MANAGEMENT AND BUDGET

Statistical Policy Directive No. 2 Addendum: Standards and Guidelines for Cognitive Interviews

AGENCY: Office of Management and Budget, Executive Office of the President.

ACTION: Notice of solicitation of comments.

SUMMARY: Under the Budget and Accounting Procedures Act of 1950 (31 U.S.C. 1104(d)) and the Paperwork Reduction Act of 1995 (44 U.S.C. 3504(e)), the Office of Management and Budget (OMB) issues for comment a proposed addendum to Statistical Policy Directive No. 2: Standards and Guidelines for Statistical Surveys (71 FR 55522, September 22, 2006). This addendum reflects the ongoing commitment of the Federal statistical system to ensure robust application across the Government of advances in survey methods.

In its role as coordinator of the Federal statistical system under the Paperwork Reduction Act, OMB, among other responsibilities, is required to ensure the efficiency and effectiveness of the system as well as the relevance, accuracy, objectivity, and confidentiality of information collected for statistical purposes. OMB is also charged with developing and overseeing the implementation of Government-wide principles, policies, standards, and guidelines concerning the development, presentation, and dissemination of statistical information. Accordingly, OMB requests comments on the recommendations that it received from the Federal Committee on Statistical Methodology (FCSM) Subcommittee on Question Evaluation Methodology for an addendum to OMB Statistical Policy Directive No. 2, Standards and Guidelines for Statistical Surveys. The addendum, Standards and Guidelines for Cognitive Interviews is intended to ensure that the results of statistical surveys sponsored by the Federal Government are as reliable and useful as possible while minimizing respondent burden. The addendum may be accessed at *www.omb.gov/inforeg/Directive_No. 2_Addendum.* Comments are also requested regarding suggestions for other aspects of statistical methodology to be considered for inclusion in future addenda to this directive.

Additional discussion of the proposed addendum may be found in the **SUPPLEMENTARY INFORMATION** section below.

DATES: Comments and recommendations on the proposed addendum detailed in this notice must be in writing. To ensure consideration of comments, they must be received no later than June 24, 2016. Please be aware of delays in mail processing at Federal facilities due to security screenings. Respondents are encouraged to send comments electronically via email, FAX, or *http://www.regulations.gov* (discussed in **ADDRESSES** below).

ADDRESSES: Please send any comments or questions about this directive to: Katherine K. Wallman, Chief Statistician, Office of Management and Budget, 1800 G St., 9th Floor, Washington, DC 20503, *telephone number:* (202) 395–3093, *FAX number:* (202) 395–7245. You may also send comments or questions via email to *Directive_No._2_Addendum@omb.eop.gov* or to *http://www.regulations.gov*—a Federal E-Government Web site that allows the public to find, review, and submit comments on documents that agencies have published in the **Federal Register** and that are open for comment. Simply type "Directive No. 2 Addendum" (in quotes) in the Comment or Submission search box, click Go, and follow the instructions for submitting comments.

Comments submitted in response to this notice may be made available to the public through relevant Web sites. For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information or proprietary information. If you send an email comment, your email address will be automatically captured and included as part of the comment that is placed in the public docket. Please note that responses to this public comment request containing any routine notice about the confidentiality of the communication will be treated as public comments that may be made available to the public notwithstanding the inclusion of the routine notice. Because of delays in the receipt of regular mail related to security screening, respondents are encouraged to use electronic communications.

Electronic Availability: This document is available on the Internet on the OMB Web site at *www.omb.gov/inforeg/Directive_No._2_Addendum.*

FOR FURTHER INFORMATION CONTACT: Jennifer Park, 1800 G St., 9th Floor, Washington, DC 20503, *email address: jpark@omb.eop.gov* with subject Directive No. 2 Addendum, *telephone number:* (202) 395–9046, *FAX number:* (202) 395–7245.

SUPPLEMENTARY INFORMATION: The Nation relies on the flow of credible statistics to support the decisions of governments, businesses, individuals, households, and other organizations. Federal surveys collect much of the information available about the United States' economy, population, natural resources, environment, and public and private institutions. It is essential that these surveys collect information in a clear, straight-forward manner so as to maximize the accuracy of data while minimizing respondent burden.

Background: Consistent with the Information Quality Act (Pub. L. 106–554, Division C, title V, Sec. 515, Dec. 21, 2000; 114 Stat. 2763A–153 to 2763A–154) and in accordance with Statistical Policy Directive No. 1: Fundamental Responsibilities of Federal Statistical Agencies and Recognized Statistical Units (79 FR 71610, Dec. 2, 2014), it is the responsibility of Federal agencies engaging in statistical work to continuously review statistical methodologies and implement improvements as they are identified so as to better ensure the relevance, accuracy, and objectivity of the statistical products our Nation uses to monitor and assess performance, progress, and needs. Further, these responsibilities must be achieved in a manner that protects the confidentiality of information acquired solely for statistical purposes. Among other requirements, Federal guidelines, such as those provided in Statistical Policy Directive No. 2: Standards and Guidelines for Statistical Surveys, recommend robust testing of survey questions before implementation.

Cognitive interviewing is a key method used to pretest survey questions and questionnaires. This method investigates whether respondents understand survey questions according to their intended design and whether respondents can provide accurate answers based on that intent. Cognitive interviews determine respondent interpretations and detail the phenomena considered by respondents in forming their answer. Findings from cognitive interviews can indicate whether a survey question captures the intended construct; cognitive interview findings can also identify difficulties that respondents experience when formulating responses. Ultimately, rigorous cognitive interviews support the efficient production of useful statistics since the findings from cognitive interviews can be used to help minimize costs and burden while ensuring the accuracy of the information collected.

Although cognitive interviews are broadly used across a variety of Federal agencies engaged in statistical activities, to date no specific Federal guidance has established the manner in which this particular method should be conducted. As such, the term "cognitive interview," when applied to Federal statistical surveys could refer to any of an array of related research techniques that differ in their appropriate use for statistical surveys. The purpose of this addendum is to establish rigorous standards for the use of cognitive interviews in Federal information collections. These standards would allow data collectors and users alike to better evaluate the quality of survey questions and the resulting survey statistics. The addendum would apply to all Federal agencies subject to the Paperwork Reduction Act of 1995. Agencies not subject to the PRA would also benefit from this addendum, and are therefore encouraged to apply this guidance as well.

Development and Review: Statistical Policy Directive No. 2: Standards and Guidelines for Statistical Surveys was issued in 2006. It remains a robust and comprehensive source of guidance to Federal agencies engaged in statistical acitivites. Specifically, Statisical Policy Directive No. 2 was issued to ensure implementation of improved survey methods across Federal agencies. To achieve this, periodic updates and addenda are required to ensure that this Directive remains most useful to Federal agencies.

Accordingly, in 2014 OMB requested members of the Federal Interagency Council on Statistical Policy (ICSP) to nominate representatives for a new subcommittee formed under the aegis of the Federal Committee on Statistical Methodology (FCSM). The Question Evaluation Methodology Subcommittee was asked to identify best practices for conducting cognitive interviews so as to improve the resulting data quality. Subcommittee members reviewed relevant scientific literature, the Paperwork Reduction Act, the Information Quality Act, Government-wide Information Quality Guidelines (Information Quality Guidelines) (67 FR 8453, Jan. 3, 2002), Statistical Policy Directive No. 1 and Directive No. 2, and other information quality standards currently used by Federal statistical agencies. Through this careful process, the subcommittee reached a consensus in identifying seven standards for cognitive interviews. The subcommittee provided draft standards and guidelines for review by the FCSM and the ICSP in 2015. The subcommittee addressed the comments it received at each stage and provided its final recommendations to the FCSM in 2015. OMB proposes the issuance of these recommendations as an addendum to Statistical Policy Directive No. 2: Standards and Guidelines for Cognitive Interviews.

Issues for Comment: With this notice, OMB requests comments on the proposed addendum, which can be accessed at *www.omb.gov/inforeg/Directive_No. 2_Addendum.* OMB seeks comments from all interested parties on all aspects of this proposed addendum. In particular, OMB seeks comment on the merit of the proposed standards and guidelines both about technical terms, such as statistical definitions, and as statistical policy. These standards and guidelines for cognitive interviews should reflect best practices for Federal agencies and their contractors in conducting statistical surveys as well as sound policy for the Federal statistical system. OMB seeks comment on whether some provisions of this proposal should be modified or deleted to meet these goals. Finally, OMB seeks comment from affected agencies on the expected benefits and burdens of the proposed addendum. Suggestions regarding other aspects of statistical methodology that should be considered as future addenda to Directive No. 2 are also encouraged.

Howard A. Shelanski,

Administrator, Office of Information and Regulatory Affairs.

[FR Doc. 2016–10958 Filed 5–9–16; 8:45 am]

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